THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s):	James D. Lewis, Jr., et al.
Appl. No.:	10/779,993
Conf. No.:	1329
Filed:	February 17, 2004
Title:	ALBUMIN IN A FLEXIBLE POLYMERIC CONTAINER
Art Unit:	3728
Examiner:	Jila M. Mohandesi
Docket No.:	HT-5755 US DIV 1 (112713-1354)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on August 14, 2007. This Appeal is taken from the Final Rejection in the Office Action dated July 24, 2007.

I. REAL PARTIES IN INTEREST

The real parties in interest for the above-identified patent application on Appeal are Baxter International Inc. and Baxter Healthcare S.A., by virtue of an Assignment dated August 18, 2004 and recorded at reel 015072, frames 0119-128 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignees of the this patent application do not know of any prior or pending appeals, interferences or judicial proceedings that may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1-12, 22, 25-26 and 28-33 are pending in this application. Claims 13-21, 23-24 and 27 were previously canceled. Claims 34-36 were previously withdrawn. Claims 1-12, 22, 25-26 and 28-33 stand rejected. Therefore, Claims 1-12, 22, 25-26 and 28-33 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A non-final Office Action was mailed on February 12, 2007. Appellants responded to the non-final Office Action on May 7, 2007, amending the claims to overcome the rejections set forth in the non-final Office Action. A final Office Action maintaining the rejections was mailed on July 24, 2007. Appellants filed a Notice of Appeal on August 14, 2007. A copy of the non-final Office Action and final Office Action are attached as Exhibits A and B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the claimed subject matter by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a container for holding albumin (page 3, lines 2-20; page 5, line 5 to page 6, line 13; page 7, lines 25-28; Figure 3) comprising a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold (page 3, lines 2-20; page 4, lines 1-8; page 8, line 32 to page 9, line 16), and permanent seals about a periphery of the first and second walls (page 3, lines 2-20; page 12, line 1 to page 13, line 6); an albumin concentration of at least about 20% in the cavity (page 4, lines 9-11; page 8, lines 18-31); a seal area free of the albumin concentration (page 16, line 21 to page 17, line 5); a permanent heat seal formed on the seal area, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container (page 3, lines 2-20; page 12, line 1 to page 13, line 6), wherein the albumin concentration of at least about 20% contacts the interior portion and is stored within the fluid-tight chamber (page 4, lines 9-11; page 5, line 5 to page 6, line 13; page 8, lines 18-31).

Independent Claim 30 is directed to a container for holding albumin (page 3, lines 2-20; page 5, line 5 to page 6, line 13; page 7, lines 25-28; Figure 3) comprising a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold (page 3, lines 2-20; page 4, lines 1-8; page 8, line 32 to page 9, line 16), and permanent seals about a portion of a periphery of the first and second walls (page 3, lines 2-20; page 12, line 1 to page 13, line 6); a seal area forming an opening to the cavity (page 5, line 29 to page 6, line 9); and an albumin concentration added through the opening so that the seal area is free of albumin concentration (page 4, lines 9-11; page 5, line 5 to page 6, line 13; page 8, lines 18-31; page 16, line 21 to page 17, line 5).

Although specification citations are given in accordance with 37 C.F.R. §1.192(c), these reference numerals and citations are merely examples of support in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims.

Pointing out specification support for the claim terminology in accordance with Rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-7, 11-12, 22, 25 and 28-33 stand rejected under 35 U.S.C. §103(a) for being unpatentable over U.S. Patent No. 4,692,361 to Johnston et al. ("*Johnston*"). A copy of *Johnston* is attached hereto as Exhibit C in the Evidence Appendix.

2. Claims 8 and 26 stand rejected under 35 U.S.C. §103(a) for being unpatentable over *Johnston* in view of U.S. Patent No. 4,910,147 to Bacehowski et al. ("*Bacehowski*"). A copy of *Bacehowski* is attached hereto as Exhibit D in the Evidence Appendix.

3. Claims 9-10 stand rejected under 35 U.S.C. §103(a) for being unpatentable over *Johnston* in view of U.S. Patent 4,936,456 to Bell et al. ("*Bell*"). A copy of *Bell* is attached hereto as Exhibit E in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal basis for a determination of obviousness under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Patent Office must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court has emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered

to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Mach. Corp. v. Fukuhara Indus. Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998) (quoting *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994)).

B. THE CLAIMED INVENTION

There are two independent claims on appeal: Claims 1 and 30. Independent Claim 1 is generally directed to a container for holding albumin comprising a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold and permanent seals about a periphery of the first and second walls. An albumin concentration of at least about 20% is provided in the cavity. A seal area of the container is free of the albumin concentration. A permanent heat seal is formed on the seal area. The seals join an interior portion of the opposing first and second walls and create a fluid-tight chamber within the cavity of the container. The albumin concentration of at least about 20% contacts the interior portion and is stored within the fluid-tight chamber.

Independent Claim 30 is generally directed to a container for holding albumin comprising a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold, and permanent seals about a portion of a periphery of the first and second walls. A seal area forms an opening to the cavity of the container. An albumin concentration is added through the opening so that the seal area is free of albumin concentration.

C. THE REJECTION OF CLAIMS 1-7, 11-12, 22, 25 AND 28-33 UNDER 35 U.S.C. §103(A) TO *JOHNSTON* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellants respectfully submit that *Johnston* fails to disclose or suggest every element of the claimed invention. Independent Claim 1 recites, in part, a flexible container containing an albumin concentration of 20%. Independent Claim 1 also recites, in part, that the container also

has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration. Independent Claim 30 recites, in part, an albumin concentration added through the opening so that the seal area is free of albumin concentration. In contrast, Appellants respectfully submit that *Johnston* fails to disclose or suggest every element of independent Claims 1 and 30.

Therapeutically useful proteins such as albumin are adsorbed to some extent by most man-made materials, including liquid containers made of various polymers. Adsorption of the albumin onto the artificial polymeric surface results in a lowering of the albumin content of that solution. In addition, albumin solutions can be adversely affected by albumin adsorption onto artificial surfaces through a process called denaturing. In one form of denaturing, a protein is not permanently adsorbed onto the polymeric container, but rather the protein molecules are adsorbed onto the container and then released. The adsorption and release can change the shape of the molecule (i.e., denature it). Often, when protein molecules in drug solutions have undergone denaturing, they may lose their efficacy and utility. Accordingly, to date proteins such as albumin have been stored for individual use in glass vials in order to avoid the risk of denaturing. However, the use of glass vials can be problematic because of the cost encountered in producing, packaging, boxing, shipping and storing glass vials, as well as the cost and weight of the glass vial, and the ease with which the glass vial may break.

One type of packaging for packaging non-protein pharmaceuticals is polymeric bags formed with a form-fill-seal packaging machine. Form-fill-seal packaging machines are typically used to package a product in a flexible container. The form-fill-seal packaging machine provides an apparatus for packaging certain pharmaceuticals and many other products inexpensively and efficiently manner.

Pursuant to FDA requirements, certain pharmaceuticals packaged in form-fill-seal packages are traditionally sterilized in a post-packaging autoclaving step. The post-packaging step includes placing the sealed package containing the pharmaceutical in an autoclave and steam sterilizing or heating the package and its contents to a required temperature, which is often approximately 250 °F, for a prescribed period of time. This sterilization step operates to kill bacteria and other contaminants found inside the package, whether on the inner layer of film or within the pharmaceutical itself. Nevertheless, certain packaged pharmaceuticals, including certain proteins such as albumin, generally cannot be sterilized in such a manner. This is

because the heat required to kill the bacteria in the autoclaving process operates to congeal the albumin, thereby rendering it therapeutically useless.

In addition, form-fill-seal packaging may also present other problems beyond sterilization concerns when packaging certain proteins such as albumin. Specifically, conventional form-fill-seal packaging machinery introduces heat to certain areas of the polymeric material of the package to create seals. If the heat contacts the protein during the sealing process, the protein may congeal or otherwise denature just as it would during high-temperature sterilization. Further, because certain proteins such as albumin operate as insulators, all seal areas must be free of the albumin for the polymeric materials to be heat sealed together. If any substance, such as albumin is present in the seal area prior to sealing, the integrity of the seal (and ultimately the sterility of the contents) may be compromised.

As a result of the previously described deficiencies of conventional glass vials containing albumin and the challenges of producing and sterilizing packaged proteins, Appellants have developed an efficient, inexpensive and user friendly methods of packaging albumin to eliminate the above drawbacks. In alternative embodiments, the present invention is directed, in part, to the novel flexible, sealed containers comprising an albumin concentration produced by these novel methods.

Regarding the current obviousness rejection, *Johnston* fails to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. *Johnston* also fails to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. In addition, *Johnston* fails to disclose or suggest an albumin concentration is added through the opening so that the seal area is free of albumin concentration as required by Claim 30. In fact, *Johnston* fails to even disclose or suggest albumin in a container anywhere in his disclosure.

Johnston merely discloses a flexible film that can be run through a form-fill-seal packaging machine to create a flexible container, the container capable of storing drug solutions or plasma. See, *Johnston*, column 6, lines 50-66 and column 2, lines 40-45. *Johnston* has no disclosure whatsoever with respect to: 1) a container containing a 20% albumin concentration; and/or 2) a container with a seal area free of the albumin concentration before heat seal formation.

The Examiner asserts that the actual product or composition to be contained in the container of *Johnston* is merely a matter of user preference and that it is entirely obvious to use whatever composition is desired. Appellants respectfully disagree: this argument thoroughly ignores the practical difficulties and problems associated with making a flexible, heat sealed container comprising a heat sensitive albumin protein solution in accordance with the present claims. Consequently, *Johnston* provides the person of ordinary skill with no reasonable expectation of success regarding the subject matter of the present claims.

For example, *Johnston* fails to recognize the problems associated with methods of heat sealing an albumin-filled flexible container. First, albumin can readily congeal or degrade and become useless after exposure to heat. As a result, the skilled artisan would be led away from heat sealing any container containing albumin. In addition, because albumin operates as an insulator, the presence of a high albumin concentration on the seal area before heat sealing would be expected to result in a compromised or weakened heat seal, which makes it difficult to manufacture heat sealed containers containing albumin. See specification, page 2 lines 23-31. The present application discloses novel and non-obvious albumin containers that overcome these problems, for example, by ensuring that the seal area is free of albumin when a heat seal is formed on the seal area. See specification, page 15 lines 4-10.

In sum, not only does *Johnston* fail to disclose or suggest every element of the present claims, *Johnston* fails to even recognize the advantages, benefits and/or properties of a heat sealed container holding albumin in accordance with the present claims. Accordingly, the novel and non-obvious processes of the present specification (see related U.S. Patent No. 6,718,735) produce the claimed containers of albumin that are novel and non-obvious as well.

For at least these reasons, *Johnston* fails to disclose or suggest every element of the present claims. Accordingly, Appellants respectfully submit that Claims 1 and 30, as well as Claims 2-7, 11-12, 22, 25, 28-29 and 31-33 that depend from Claims 1 and 30, are novel, nonobvious and distinguishable from the cited reference and are in condition for allowance.

D. THE REJECTION OF CLAIMS 8 AND 26 UNDER 35 U.S.C. §103(A) TO *JOHNSTON* AND *BACEHOWSKI* IS IMPROPER IN VIEW OF THE PATENTABILITY OF INDEPENDENT CLAIM 1

Claims 8 and 26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Johnston* and *Bacehowski*. Appellants respectfully submit that the patentability of Claim 1 over *Johnston* as discussed above also demonstrates that the obviousness rejection of Claims 8 and 26, which depend from Claim 1, is improper. Even with *Bacehowski* as an additional reference, the cited art fails to teach or suggest the elements of Claims 8 and 26 in combination with the novel elements of Claim 1.

For example, *Johnston* and *Bacehowski* fail to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. *Johnston* and *Bacehowski* also fail to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. In addition, *Johnston* and *Bacehowski* fail to disclose or suggest an albumin concentration that is added through the opening so that the seal area is free of albumin concentration as required by Claim 30. In fact, *Bacehowski* has no disclosure whatsoever directed to a flexible container that contains an albumin concentration or even the term "albumin." Because *Bacehowski* lacks any disclosure of albumin whatsoever, *Bacehowski* cannot disclose or remotely suggest 1) an albumin-filled flexible container 2) with a seal area free of the albumin concentration in accordance with the present claims.

Accordingly, Appellants respectfully submit that Claims 8 and 26 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

E. THE REJECTION OF CLAIMS 9-10 UNDER 35 U.S.C. §103(A) TO *JOHNSTON* AND *BELL* IS IMPROPER IN VIEW OF THE PATENTABILITY OF INDEPENDENT CLAIM 1

Claims 9-10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Johnston* and *Bell*. Appellants respectfully submit that the patentability of Claim 1 over *Johnston* as discussed above also demonstrates that the obviousness rejection of Claims 9-10, which depend

from Claim 1, is improper. In this regard, even with *Bell* as a reference, the cited art fails to teach or suggest the elements of Claims 9-10 in combination with the novel elements of Claim 1.

For example, *Johnston* and *Bell* fail to disclose or suggest a flexible container containing an albumin concentration of 20% as required by Claim 1. *Johnston* and *Bell* also fail to disclose or suggest that the container has a seal area free of the albumin concentration and a heat seal formed on the seal area to create a fluid-tight chamber for the albumin concentration as required by Claim 1. In addition, *Johnston* and *Bell* fail to disclose or suggest an albumin concentration is added through the opening so that the seal area is free of albumin concentration as required by Claim 30. Moreover, *Bell* not only fails to disclose or suggest albumin anywhere in his disclosure, *Bell* teaches away from the flexible container having permanent peripheral seals as recited in the present claims. For example, *Bell* discloses a flexible bag made with peripheral peel seals, which teaches away from a container having permanent seals in accordance with the present claims. See, *Bell*, column 5, line 60 to column 6, line 16 and Figure 1. Teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Consequently, any combination with *Bell* is likewise *per se* non-obvious.

Accordingly, Appellants respectfully submit that Claims 9-10 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejections of Claims 1-12, 22, 25-26 and 28-33. Accordingly, Appellants respectfully submit that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

A check in the amount of $500 is submitted herewith to cover the cost of the Appeal Brief. The Director is authorized to charge any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112713-1354 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

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Dated: October 11, 2007

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/779,993

1. A container for holding albumin comprising:

a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold, and permanent seals about a periphery of the first and second walls;

an albumin concentration of at least about 20% in the cavity;

a seal area free of the albumin concentration;

a permanent heat seal formed on the seal area, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container, wherein the albumin concentration of at least about 20% contacts the interior portion and is stored within the fluid-tight chamber.

2. The container of claim 1, wherein a solution of sterile water and stabilizers is mixed with the concentration of albumin in the container.

3. The container of claim 1, wherein the bag has a plurality of peripheral edges that are sealed, and another peripheral edge that contains the fold.

4. The container of claim 3, wherein three of the peripheral edges are sealed with heat, and one of the peripheral edges contains the fold that separates the first wall from the opposing second wall.

5. The container of claim 3, wherein a fitment is connected to the container, the fitment having a passageway that cooperates with the fluid-tight chamber of the container.

6. The container of claim 5, wherein the fitment is adjacent the fold.

7. The container of claim 3, wherein the peripheral edge opposing the fold contains a first longitudinal seal and a second longitudinal seal, the first and second longitudinal seals joining the first and second opposing walls, and wherein an aperture is located between the first longitudinal seal and the second longitudinal seal, the aperture extending through the first and second opposing walls.

8. The container of claim 3, further comprising an aperture adjacent an edge opposing the fitment.

9. The container of claim 3, further comprising at least one chevron seal in the fold.

10. The container of claim 5, further comprising a chevron seal in the fold on opposing sides of the fitment.

11. The container of claim 1, wherein the flexible polymeric film comprises a laminate having an outside layer of linear low density polyethylene, a gas barrier layer, a core layer of polyamide, and an inside layer of linear low density polyethylene.

12. The container of claim 11, wherein the layers comprising the flexible polymeric film are bonded together with a polyurethane adhesive.

22. The container of claim 1 wherein the albumin concentration is about 25%.

25. The container of claim 1 wherein the albumin concentration is selected from the group consisting of a stabilized albumin solution, a pasteurized albumin solution, and combinations thereof.

26. The container of claim 8 comprising a seal disposed between the chamber and the aperture.

28. The container of claim 1 wherein the permanent heat seal has a seal strength of at least 20 psi.

29. The container of claim 1 wherein the film is a peroxide sterilized film.

30. A container for holding albumin comprising:

a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall joined thereto at a fold, and permanent seals about a portion of a periphery of the first and second walls;

a seal area forming an opening to the cavity; and

an albumin concentration added through the opening so that the seal area is free of albumin concentration.

31. The container of claim 30 comprising a permanent heat seal on the seal area, the seals forming a fluid tight chamber within the cavity.

32. The container of claim 31 wherein the seals have a seal strength of at least 20 psi.

33. The container of claim 30 wherein the albumin concentration is at least about 20%.

EVIDENCE APPENDIX

EXHIBIT A: Non-final Office Action dated February 12, 2007

EXHIBIT B: Final Office Action dated July 24, 2007

EXHIBIT C: U.S. Patent No. 4,692,361 to Johnston et al. ("*Johnston*"), cited by the Examiner in the Office Action dated July 24, 2007

EXHIBIT D: U.S. Patent 4,910,147 to Bacehowski et al. ("*Bacehowski*"), cited by the Examiner in the Office Action dated July 24, 2007

EXHIBIT E: U.S. Patent No. 4,936,456 to Bell et al. ("*Bell*"), cited by the Examiner in the Office Action dated July 24, 2007

RELATED PROCEEDINGS APPENDIX

None

EXHIBIT A

1DF D/

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV	1329

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ART UNIT	PAPER NUMBER
3728	

Due: 5-12-07

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,993	LEWIS ET AL.	
	Examiner	Art Unit	
	Jila M. Mohandesi	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 22-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361). Johnson '361 discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, permanent seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container and a fitment (see column 6, lines 57-61). See Figures 1 and 2 embodiments and column 1, lines 11-21. Johnson '361 discloses that the flexible containers are utilized in medical industry for containing, inter alias,

parenteral solutions, dialysis solutions, frozen drugs and plasma. Cruise '975 discloses that it is desirable to store albumin (at least about 20% albumin) in separate containers and flexible bags (146), see Figure 7B embodiment. Regarding the actual product or composition (concentration of at least 20% albumin), the actual composition is merely a matter of user preference and entirely obvious to use whatever composition as desired. The flexible polymeric bag of Johnston '361 is capable of holding concentration of at least 20% albumin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to store albumin concentrations in the flexible polymeric bag of Johnston '361, since the bag of Johnston '361 is suitable and utilized in the medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma (which contains albumin).

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49.

The limitation under Official Notice is now taken as admitted prior art, therefore, with respect to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the admitted prior art to mix albumin with sterilized water and stabilizers.

4. Claims 8, 13 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Johnston '361 as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as described above discloses all the limitations of the claims except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with

an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

5. Claims 9-10 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston '361 as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitation of the claims except for it is silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively log tabs are formed to facilitate opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

Response to Arguments

6. . Applicant's arguments with respect to claims 1-13 and 22-27 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M. Mohandesi whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jila M Mohandesi
Primary Examiner
Art Unit 3728

JMM
February 07, 2007

EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV	1329

29200 7590 07/24/2007
BAXTER HEALTHCARE CORPORATION
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DF2-2E
DEERFIELD, IL 60015

EXAMINER	
MOHANDESI, JILA M	
ART UNIT	PAPER NUMBER
3728	

MAIL DATE	DELIVERY MODE
07/24/2007	PAPER

Due: 10-24-07: FINAL OA

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

7.26.07 EHY

Office Action Summary	Application No.	Applicant(s)	
	10/779,993	LEWIS ET AL.	
	Examiner	Art Unit	
	/Jila M. Mohandesi/	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,22,25,26 and 28-36* is/are pending in the application.

4a) Of the above claim(s) *34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,22,25,26 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 34-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are directed to a way of filling the flexible bag and not the flexible bag itself.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7, 11-12, 22, 25 and 28-33 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361). Johnson '361 discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, permanent seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container and a fitment (see column 6, lines 57-61). See Figures 1 and 2 embodiments and column 1, lines 11-21.

Johnson '361 discloses that the flexible containers are utilized in medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma. Regarding the actual product or composition (concentration of at least 20% albumin), the actual composition is merely a matter of user preference and entirely obvious to use whatever composition as desired. The flexible polymeric bag of Johnston '361 is capable of holding concentration of at least 20% albumin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to store albumin concentrations in the flexible polymeric bag of Johnston '361, since the bag of Johnston '361 is suitable and utilized in the medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma (which contains albumin).

It is noted that, in the seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this seal is formed prior to filling of the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tube area, see column 6, lines 57-61 and Figure 2 embodiment.

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49.

With respect to claim 29, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

The limitation under Official Notice is now taken as admitted prior art, therefore, with respect to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the admitted prior art to mix albumin with sterilized water and stabilizers.

With respect to claims 28 and 32 and the strength of the seal, this would be a design choice depending on the strength desired and cost of manufacturing.

4. Claims 8 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Johnston '361 as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as described above discloses all the limitations of the claims except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

5. Claims 9-10 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston '361 as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitation of the claims except for it is silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively log tabs are formed to facilitate

opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

Response to Arguments

6. Applicant's arguments filed 05/07/2007 have been fully considered but they are not persuasive.

The seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this seal is formed prior to filling of the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tube area, see column 6, lines 57-61 and Figure 2 embodiment.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Jila M. Mohandesi/ whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jila M Mohandesi/
Primary Examiner
Art Unit 3728

JMM
July 16, 2007

EXHIBIT C

United States Patent [19]

Johnston et al.

[11] **Patent Number: 4,692,361**

[45] **Date of Patent: Sep. 8, 1987**

[54] **FILM LAMINATE WITH GAS BARRIER FOR STERILE FLEXIBLE CONTAINERS**

[75] Inventors: **William D. Johnston**, Buffalo Grove; **Leonard Czuba**, Lombard; **R. D. Webster**, Barrington, all of Ill.; **Yasuhiko Hori**, Kawasaki, Japan; **Masanori Nagata**, Tokyo, Japan; **Shigeki Imano**, Kawasaki, Japan

[73] Assignee: **Baxter Travenol Laboratories, Inc.**, Deerfield, Ill.

[21] Appl. No.: **655,493**

[22] Filed: **Sep. 28, 1984**

[51] **Int. Cl.**[4] **B65D 85/72**; B32B 27/08

[52] **U.S. Cl.** **428/35**

[58] **Field of Search** 428/423.5, 424.6, 424.8, 428/475.8, 35, 36; 383/113; 604/408

[56] **References Cited**

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0067420 12/1982 European Pat. Off. .

Primary Examiner—John E. Kittle

Attorney, Agent, or Firm—John P. Kirby; Paul C. Flattery; Robert M. Barrett

[57] **ABSTRACT**

A film laminate for flexible containers capable of containing a product to be maintained and removed under sterile conditions. The film laminate having an outside layer of linear low density polyethylene, a gas barrier layer, a core layer of polyamide, and an inside layer of linear low density polyethylene. The layers being bonded together by a polyurethane adhesive.

34 Claims, 2 Drawing Figures

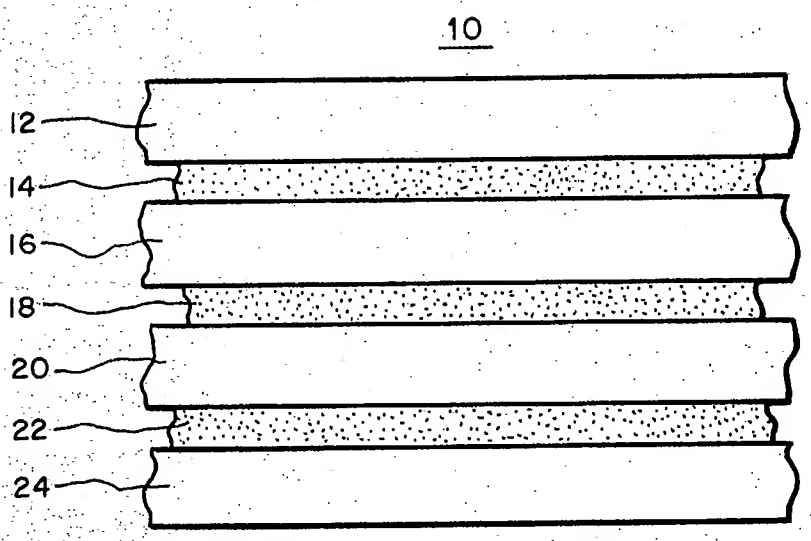


FIG. 1

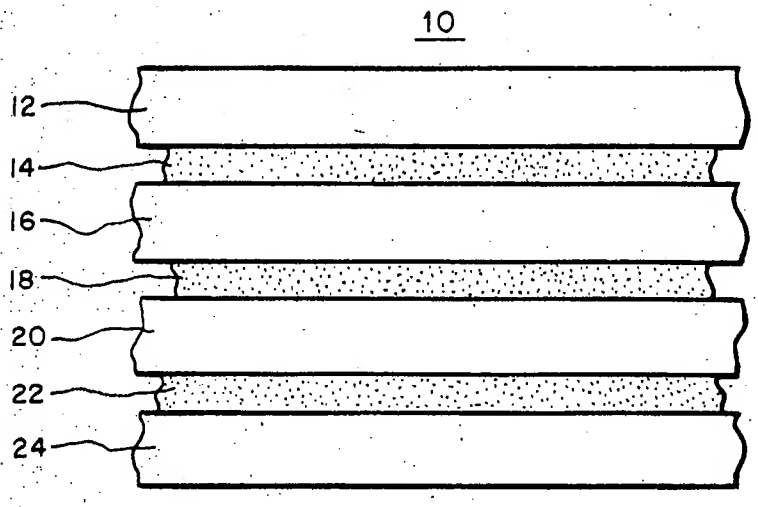
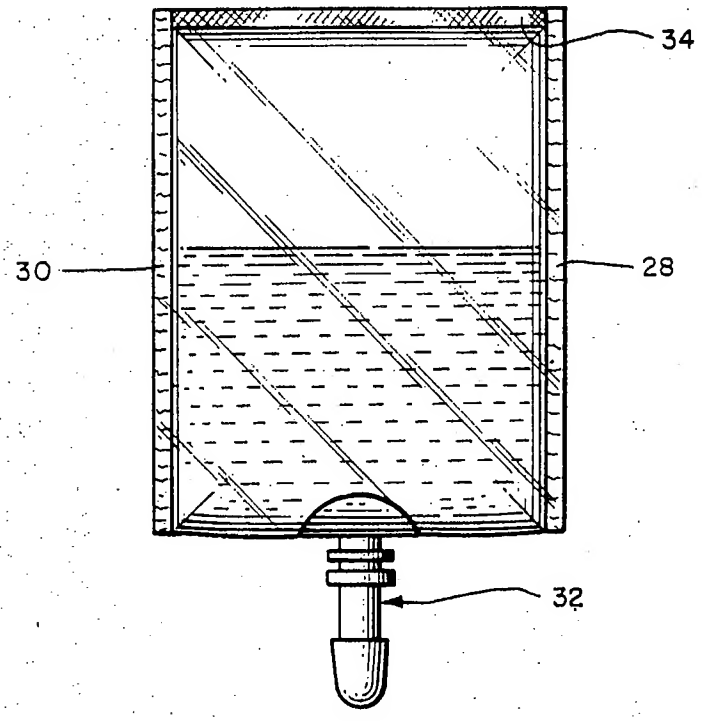


FIG. 2



FILM LAMINATE WITH GAS BARRIER FOR STERILE FLEXIBLE CONTAINERS

BACKGROUND OF THE INVENTION

This invention relates to a film laminate structure for flexible containers. In particular, this invention relates to a multilayer high barrier laminate film structure for flexible containers capable of containing a product to be maintained and removed under sterile conditions.

Flexible containers are utilized in the medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma. Because these containers are utilized to contain fluids or solids that are introduced into a patient's body, it is necessary for the containers to be; essentially transparent; flexible; essentially free of extractables; and capable of maintaining the product contained therein under sterile conditions until the product is accessed or removed from the flexible container.

It is also important that the film used in constructing these containers is sufficiently strong so that the containers constructed from the film have sufficient strength. Moreover, if the laminate film is to be constructed into a commercially viable flexible container, it is necessary that the flexible film can be run on some type of commercial production machine. One such machine is a form, fill and seal packaging machine. A form, fill and seal packaging machine requires that the film be sealable on at least two sides. The side seals are typically effectuated by sealing the inside layer of the film to itself.

It may also be desirable to attach a fitment on the film structure to create a flexible container with a fitment. The fitment is typically heat sealed to the film. Accordingly, it may also be necessary that the film structure is heat sealable on its outside layer so that the fitment may be sealed thereto.

Because the film laminate is to be utilized for flexible containers that house a medical product that is to be introduced into a patient's body, it is necessary that the film structure does not contain chemicals that will be extracted by the medical product. This is an especially critical consideration when choosing an adhesive for bonding the laminate layers together. If a fitment is utilized and sealed to the outside layer of the film it is possible that there will be fluid communication between the product and the layers of the laminate. Thus, if the adhesive contains possible hazardous components that may be extractable the film may not include a fitment sealed to the outside well.

A further consideration in choosing the proper film for creating a flexible container is the product to be housed. In applications of the film to produce containers for products stored at room temperature, it is necessary that the film provides a container with sufficient barrier properties. Without a sufficient barrier, water vapor, oxygen, and other gases and vapors may permeate the film inactivating or degrading the product contained therein.

Thus, there is a need for a film laminate structure for creating a sterile flexible container that overcomes the disadvantages of the prior art.

SUMMARY OF THE INVENTION

The present invention provides a film laminate for flexible containers capable of containing a product to be maintained and removed under sterile conditions. The film laminate comprises an outside layer of linear low density polyethylene, a gas barrier layer, a core layer of biaxially oriented nylon, an inside layer of linear low density polyethylene, and three layers of a polyurethane adhesive that bonds the outside, inside, gas barrier, and core layers together.

Preferably the inside and outside layers have a thickness of approximately 40 to about 100 microns, the gas barrier layer has a thickness of approximately 20 to about 50 microns, and the core layer has a thickness of approximately 10 to about 40 microns. The polyurethane adhesive layers preferably have a thickness of approximately 1 to about 10 microns. The preferred thickness of the film laminate is approximately 155 to about 230 microns. Preferably the inside and outside layers have a density of approximately 0.91 to 0.94 grams/cubic centimeters.

In a preferred embodiment the film laminate can be formed into, and function as a container for products maintained at room temperature. The preferred material for the gas barrier is polyvinylidene chloride.

The outside and inside layers of the film laminate preferably include an antioxidant, stabilizer, antiblocking agent, and slip agent.

Accordingly, it is an advantage of the present invention to provide a multilayer laminate structure that may be utilized to create a sterile flexible container.

Another advantage of the present invention is to provide a film structure that is sealable on its inside and outside layers.

A still further advantage of the present invention is that it provides a film that can be utilized to produce a container having a fitment heat sealed on the outside wall.

An additional advantage of the present invention is to provide a film laminate structure that includes an adhesive that may be utilized to house medical products.

Moreover, an advantage of the present invention is to provide a film laminate structure that can be utilized to produce a flexible bag that may house parenteral products including intravenous solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma.

A further advantage of the present invention is to create a film laminate structure that can be utilized in a form, fill and seal packaging machine to create a flexible container.

A still further advantage of the present invention is to create a film laminate structure that has sufficient strength to create flexible containers for housing medical products.

Another advantage of the present invention is that it provides a film that has a gas and vapor barrier.

A still further advantage of the present invention is that it provides a film that can be utilized to produce flexible containers for housing drugs and products maintained at temperatures aove 0° C.

A further advantage of the present invention is that it provides a four layer laminate film with three adhesive layers that may be utilized to produce a sterile flexible container.

Moreover, an advantage of the present invention is that the film laminate has a thickness of approximately 155 to about 230 microns.

A still further advantage of the present invention is that it provides an outside layer and inside layer con-

structed from a linear low density polyethylene containing a minor amount of a copolymerizing olefin such as 1-hexene, and including a stabilizer, an antiblock agent, an antioxidant, and a slip agent.

Another advantage of the present invention is that it provides an economical alternative to presently available high barrier films.

Additional features and advantages are described in, and will be apparent from, the Detailed Description of the Presently Preferred Embodiments and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a schematic cross-sectional view of an embodiment of the film laminate structure of this invention.

FIG. 2 illustrates a perspective view of a flexible container constructed from the film laminate of this invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The film structure of the present invention is utilized to produce flexible containers capable of containing a fluid or solid to be maintained and removed under sterile conditions. These containers typically consist of a liquid containment body defined by thermally sealed walls. The containers are utilized to package, inter alia, parenteral products including intravenous solutions dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma. The preferred film structure of this invention is a multilayer laminate structure designed to package parenteral products including intravenous solutions, dialysis solutions, nutrition products, respiratory therapy products, and plasma.

Referring to FIG. 1, a presently preferred embodiment of the film laminate structure **10** of the present invention is illustrated. The film laminate structure **10** includes an outside layer **12**, a first adhesive layer **14**, a gas barrier **16**, a second adhesive layer **18**, a core layer **20**, a third adhesive layer **22**, and an inside layer **24**. As will be described in more detail below, the adhesive layers **14**, **18** and **22** bond the outside and gas barrier layers **12** and **16**, the gas barrier and core layers **16** and **20**, and the core layer and inside layers **20** and **24** respectively. As also discussed in more detail below, as illustrated in FIG. 2, the film laminate structure **10** may be utilized to create a flexible container **26**.

The outside and inside layers **12** and **24** are constructed from a polyethylene polymer. Preferably, the outside and inside layers **12** and **24** are a linear low density polyethylene. As used herein, linear low density means that the polyethylene is made by low pressure polymerization and has a density between approximately 0.91 to about 0.94 grams/cubic centimeter. The preferred density of the linear polyethylene is between approximately 0.915 to about 0.93.

The preferred linear low density polyethylene contains approximately 2% to about 10% by weight 1-hexene. In a most preferred embodiment, the polyethylene copolymer contains approximately 5% by weight 1-hexene. Other olefinic comonomers with 4 to 18 carbon atoms also function satisfactorily. Examples of these olefins are 1-octene, 1-butene, 1-pentene, and 4-methyl-1-pentene which may be present as approximately 5% to about 11% by weight of the linear low density polyethylene.

Because the film laminate **10** is to be utilized to produce flexible containers **26** through a commercial packaging machine, it is important that the outside layer **12** has a sufficiently low coefficient of friction. The outside layer **12** must have a low coefficient of friction to ensure that it flows smoothly through the processing machine, e.g., a form, fill and seal packaging machine. Preferably the outside layer **12** has a coefficient of friction of approximately 0.2 to about 0.4 as measured by ASTM test D-1894 between the outside layer and a stainless steel surface. The preferred coefficient of friction of the outside layer **12** is approximately 0.25.

To provide the linear low density polyethylene with a sufficiently low coefficient of friction the polyethylene copolymer is slip modified by adding a fatty acid amide additive that acts like a lubricant and lowers the coefficient of friction of the film **10**. The preferred fatty acid amides have 8 to 22 carbon atoms. Oleic amide has been found to modify the linear low density polyethylene sufficiently to produce the required coefficient of friction. Preferably approximaley 0.03% to about 0.15% by weight of oleic amide is added to the linear low density polyethylene.

An important consideration for the outside layer **12** and inside layer **24** is their thickness. In order to create a flexible container **26** the inside layer **24** must be sealed to itself on at least two walls **28** and **30**. Moreover, if a fitment **32** is to be attached to the flexible container **26** it may be desirable that the fitment **32** is heat sealed to the outside layer **12**. Preferably, the outside layer **12** and inside layer **24** have a thickness of between approximately 40 to about 100 microns. The preferred thickness of the outside and inside layers **12** and **24** is between approximately 50 and about 70 microns. This thickness affords: a good heat seal; good clarity; pinhole resistance; a good tensile strength; sufficient impact strength; and provides good flexibility for the film laminate **10**.

It is not necessary that the outside layer **12** and inside layer **24** have the same thickness. However, if the outside layer **12** and inside layer **24** have the same thickness, and the layers have approximately the same coefficient of friction, this provides a film structure that resists curl and is a more versatile film laminate **10** in that it may be fed into the packaging machine with either side facing in either direction.

The linear low density polyethylene layers **12** and **24** provide properties to the film laminate structure **10** that allows the laminate to be utilized to produce a frozen drug bag. The low temperature properties, as well as the excellent heat sealability of linear low density polyethylene makes it suitable for use in producing a frozen drug bag. These properties are important in view of the fact that the temperature of the frozen drug bag when it is shipped is −25° C. For typical prior art flexible containers, e.g., those made from polyvinyl chloride, at this temperature the containers fall below the glass transition state, and therefore the materials of which the containers are made are very brittle. Therefore, flexible bags made from polyvinyl chloride may easily break. In contrast, linear low density polyethylene's glass transition state is below −80° C. and accordingly, when used as a frozen drug bag it will not fall below its glass transition state.

Preferably, the outside layer and inside layer **12** and **24** contain an antioxidant. The antioxidant functions to provide needed properties when the resin pellets are produced. Four antioxidants have been found to pro-

vide satisfactory results: tetrakis[methylene-3-(3',5'-di-tert-butyl-4'-hydroxy phenyl)propionate]methane (manufactured by Ciba-Geigy under the name Irganox 1010); n-octadecyl-beta-(4'-hydroxy-3',5'-di-tert-butyl phenyl)propionate (manufactured by Ciba-Geigy under the name Irganox 1076); butylated hydroxytoluene; 1,3,5-trimethyl-2,4,6-tris[3,5-di-tert-butyl-4-hydroxybenzyl]benzene ("Ethyl" antioxidant 330 manufactured by Ethyl Corporation); and tetrakis(2,4-di-tert-butylphenyl)-4-4'-biphenylene diphosphate (manufactured by Sandoz under the name Sandostab P-EPQ). The preferred antioxidants are Irganox 1010 and P-EPQ. Preferably approximately 0.03% to about 0.15% by weight of the antioxidant are added to the linear low density polyethylene copolymer.

The linear low density polyethylene preferably also contains a stabilizer and an antiblocking agent. The stabilizer provides needed properties during the production of the film from the resin pellets. Preferably the stabilizer is calcium stearate and comprises approximately 0.02% to about 0.06% by weight of the polyethylene. The antiblocking agent prevents the film from sticking together. Preferably the antiblocking agent is magnesium silicate and comprises approximately 0.11% to about 0.15% by weight. Other antiblocking agents that have been found to produce satisfactory results are aluminum hydroxide and magnesium hydroxide.

The gas barrier layer **16** of the film laminate **10** functions to provide a high barrier laminate. Because of the gas barrier layer **16** the film laminate **10** is highly impermeable to water, oxygen, and other fluids. This allows the film laminate **10** to be utilized to create flexible containers **30** that can house drugs and other products that are maintained or stored at temperatures above 0° C. Specifically, the film laminate **10** can be utilized to create flexible containers **26** for housing medical products stored at room temperature.

The preferred material for the gas barrier is polyvinylidene chloride (PVDC) manufactured by Dow Chemical and sold under the trademark SARAN. Dow Chemical's PVDC film X01621.10 has been found to produce satisfactory results as has a PVDC film manufactured by Asahi Kasei Kogyo Co., of Japan. The gas barrier may also be constructed from a hydrolized ethylene vinyl acetate.

Preferably the gas barrier has a thickness of approximately 18 to about 60 microns. Most preferably, the gas barrier has a thickness of approximately 25 to 50 microns.

The core layer **20** of the present invention is a polyamide, preferably nylon. The preferred nylon for the core layer **20** is a biaxially oriented nylon. A biaxially oriented nylon 6, such as the one manufactured by Unitika Ltd. of Osaka, Japan has been found to produce satisfactory results. Other nylons may also be utilized. Examples of such nylons are nylon 6-6, nylon 11, and nylon 12. All of these nylons may be either oriented or cast films.

As used herein, biaxially oriented nylon means that the nylon film has been extruded and stretched in both directions. This ensures that the molecules of nylon are biaxially oriented. This provides the film laminate structure **10** with increased mechanical qualities, i.e. pinhole resistance; tear resistance (resistance to the start of a tear); and stretch resistance.

Preferably, the core layer **20** has a thickness of between approximately 10 to about 40 microns. The preferred thickness of the core layer **20** is approximately 15 to about 20 microns. Preferably, the biaxially oriented nylon includes a slip agent. The preferred slip agent is silicon dioxide.

The first adhesive layer **14** bonds the outside layer **12** to the gas barrier layer **16**, the second adhesive layer **18** bonds the gas barrier layer **16** to the core layer **20**; and the third adhesive layer **22** bonds the inside layer **26** and core layer **20** to each other. Preferably the adhesive is an aliphatic polyurethane. The preferred aliphatic polyurethane is a polyester-urethanediol resin manufactured by Takeda Chemical Industries Co., Ltd. under the name Takelac A-385 or Takelac A-520. The preferred aliphatic polyurethane sealer layers **14**, **18** and **22** also include a hardener, Takenate A-50 manufactured by Takeda Chemical Industries Co., Ltd., comprising 3-isocyanatomethyl-3,5,5-trimethyl cyclohexyl isocyanate adduct trimethylol propane or 1,3-bis-(isocyanatomethyl)benzene adduct of trimethylol propane, and a solvent ethyl acetate.

The adhesive layers **14**, **18** and **22** create a strong bond between the polyethylene layers **12** and **24**, the gas barrier layer **16**, and the core layer **20**. Preferably the peel strength of the bond is at least 500 gms/inch of force to delaminate. The aliphatic polyurethane adhesive layers **14**, **18** and **22** also provide the following desirable properties to the laminate film structure **10**: transparency; flexibility; low temperature resistance; processability; initial tackiness; and pinhole resistance.

The preferred thickness of each of the adhesive layers **14** and **16** is approximately 1 to about 10 microns. The most preferred thickness of each of the adhesive layers **14**, **18** and **22** is approximately 3 to about 5 microns.

It has been found that the adhesive layers **14**, **18** and **22** may be utilized even if a fitment **32** is attached to the outside layer **12**. If the fitment **32** is attached to the outside layer **12**, the product within the container **26** will be in fluid communication with the adhesive layers **14**, **18** and **22**.

The total thickness of the film laminate **10** is preferably approximately 155 to about 230 microns. This provides a film laminate that: is flexible; has good strength; has good heat seals; good clarity; and sufficient impact strength.

The film laminate **10** of this invention is preferably produced by dry lamination. Preferably, a dry lamination process utilizing a two-component curing system is utilized. The adhesive is tacky at the time of combination, and curing occurs at a controlled temperature.

Referring now to FIG. **2**, the flexible container **26** constructed from the film laminate **10** of this invention is illustrated. As illustrated, the inside layer **24** is heat sealed together on itself to create walls **28**, **30** and **34**. Due to the construction of the inside layer **24**, a strong heat seal is created.

Also, as illustrated, a fitment **32** may be sealed to the outside layer **12** of the container **26**. Preferably, the fitment **32** is heat sealed to the outside layer **12**. Due to the construction of the outside layer **12**, a strong heat seal is created.

Thus, the present invention creates a film laminate structure **10** that can run through a form, fill and seal packaging machine to create flexible containers **26** including a fitment **32** that can house a medical product to be maintained and extracted under sterile conditions.

By way of example, and not limitation, examples of the film laminate **10** will now be set-forth:

EXAMPLE 1

Step 1

Laminate a 25 micron film of Dow PVDC film X01621.10 to a 15 micron film of oriented nylon 6 polymer (the nylon 6 includes a silicon dioxide as a slip agent) using 3–4 microns of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 2

Laminate a 60 micron blown film of linear low density polyethylene (the polyethylene has 5% by weight 1-hexene as its copolymer component and the following additives: antioxidants-Irganox 1010 and P-EPQ, stabilizer-calcium stearate, antiblock-magnesium silicate and slip agent-oleic amide) to the laminate made in Step 1 using 3–4 microns of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 3

Take the three layer laminate made in Step 2 and using the same dry bonding lamination process, laminate another 60 micron layer of the same polyethylene mentioned above to the other side of the laminate film. In each step, the adhesive is applied to the laminate film and "dried" before combining with the polyethylene.

Step 4

The four layer laminate is then cured in a controlled temperature environment such as an oven to completely cure the adhesive layers and allow full bonding of the layers.

EXAMPLE 2

Step 1

Laminate a 50 micron film of Dow PVDC film X01621.10 to a 15 micron film of oriented nylon 6 polymer (the nylon 6 includes a silicon dioxide as a slip agent) using 3–4 microns of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 2

Laminate a 60 micron blown film of linear low density polyethylene (the polyethylene has 5% by weight 1-hexene as its copolymer component and the following additives: antioxidants-Irganox 1010 and P-EPQ, stabilizer-calcium stearate, antiblock-magnesium silicate and slip agent-oleic amide) to the laminate made in Step 1 using 3–4 microns of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 3

Take the three layer laminate made in Step 2 and using the same dry bonding lamination process, laminate another 60 micron layer of the same polyethylene mentioned above to the other side of the laminate film. In each step, the adhesive is applied to the laminate film and "dried" before combining with the polyethylene.

Step 4

The four layer laminate is then cured in a controlled temperature environment such as an oven to completely cure the adhesive layers and allow full bonding of the layers.

It should be understood that various changes and modifications to the preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

We claim:

1. A laminate film structure having sufficient flexibility, strength, heat sealability, and slip properties for producing on a packaging machine flexible containers having fitments attached thereto and capable of containing a liquid to be maintained under sterile conditions comprising:
- an inner layer constructed from polyethylene, the inner layer having a thickness of approximately 40 to 100 microns;
- a gas barrier layer having a thickness of approximately 25 to 50 microns;
- a core layer constructed from biaxially oriented polyamide, the core layer having a thickness of approximately 10 to 40 microns;
- an outer layer constructed from polyethylene and having a thickness of approximately 40 to 100 microns, the outer layer including a slip agent and having a coefficient of friction of approximately 0.2 to about 0.4; and
- three layers of an aliphatic polyurethane bonding the layers together.

2. The film structure of claim 1 wherein the polyethylene is a linear low density polyethylene.

3. The film structure of claim 2 wherein the polyethylene copolymer contains approximately 2% to 10% by weight 1-hexene.

4. The film structure of claim 1 wherein the gas barrier is a polyvinylidene chloride.

5. The film structure of claim 2 wherein the density of the linear low density polyethylene copolymer layers is approximately 0.91 to about 0.94 grams/cubic centimeters.

6. The film structure of claim 2 wherein the linear low density polyethylene layers include the following additives:
- an antioxidant;
- a stabilizer;
- a slip agent; and
- an antiblocking agent.

7. The film structure of claim 1 wherein the aliphatic polyurethane adhesive has a thickness of between approximately 1 to about 10 microns.

8. The film structure of claim 7 wherein the bond strength of the polyethylene layers to the gas barrier layer and core layer is at least 500 gms/inch of force to delaminate.

9. The film structure of claim 1 wherein the thickness of the film structure is approximately 155 to about 230 microns.

10. A film structure having sufficient flexibility, strength, heat sealability, and slip properties for producing on a packaging machine a flexible container for containing a liquid to be administered into a patient's body comprising:
- a layer of a linear low density polyethylene copolymer for forming an outside layer of the flexible container;
- a layer of polyvinylidene chloride for forming a gas barrier layer;
- a layer of biaxially oriented nylon for forming a core layer of the flexible container;

a layer of a linear low density polyethylene copolymer for forming an inside layer of the flexible container; and

the layers being bonded by a polyurethane adhesive.

11. The film structure of claim **10** wherein the polyethylene layers that comprise the outside and inside layers of the flexible container have a density of between approximately 0.91 to about 0.94 grams/cubic centimeters.

12. The film structure of claim **10** wherein the outside layer includes approximately 0.05% to about 0.15% by weight of a fatty acid amide containing 8 to 22 carbon atoms.

13. The film structure of claim **12** wherein the fatty acid amide is an oleic amide.

14. The film structure of claim **10** wherein the outside layer has a coefficient of friction of between 0.2 to 0.4.

15. The film structure of claim **10** wherein the polyurethane adhesive comprises a polyester-urethanediol resin.

16. The film structure of claim **15** wherein the layers are bonded to each other at a peel strength of at least 500 gms/inch of force to delaminate.

17. The film structure of claim **10** wherein the linear low density polyethylene copolymers that comprise the outside and inside layers of the flexible container include:

an antioxidant;

a slip agent;

a stabilizer; and

an antiblocking agent.

18. The film structure of claim **17** wherein:

the antioxidant is selected from the group consisting of tetrakis[methylene-3-(3'5'-di-tert-butyl-4'-hydroxy phenyl)propionate]methane, n-octadecyl-beta-(4'-hydroxy-3',5'-di-tert-butylphenyl)propionate, butylated hydroxytoluene, Ethyl antioxidant 330, and tetrakis(2,4-di-tert-butylphenyl)-4,4'-biphenylene disphosphonite;

the stabilizer is calcium stearate; and

the anti-blocking agent is selected from the group consisting of magnesium hydroxide, aluminum hydroxide, and magnesium silicate.

19. The film structure of claim **10** wherein:

the outside layer has a thickness of approximately 40 to about 100 microns;

the inside layer has a thickness of approximatly 40 to about 100 microns;

the gas barrier layer has a thickness of approximately 25 to about 50 microns; and

the core layer has a thickness of approximately 10 to about 40 microns.

20. The film structure of claim **19** wherein the thickness of the film structure is approximately 155 to about 230 microns.

21. The film structure of claim **10** wherein the polyvinylidene chloride is SARAN.

22. A flexible container capable of containing under sterile conditions a fluid or solid to be stored at temperatures above 0° C. having a body portion with opposed, peripherally sealed walls forming the container the walls being constructed from a laminate comprising:

an outside layer constructed from linear low density polyethylene;

a gas barrier layer constructed from polyvinylidene chloride;

a core layer constructed from biaxially oriented nylon;

an inside layer constructed from linear low density polyethylene; and

three layers of a urethane adhesive for bonding the outside, vapor barrier, core, and inside layers.

23. The flexible container of claim **22** wherein the outside layer and inside layer have a density of approximately 0.91 to about 0.94 grams/cubic centimeters.

24. The flexible container of claim **22** wherein the film laminate has a thickness of approximately 150 to about 200 microns.

25. The flexible container of claim **22** wherein the outside layer contains a slip agent.

26. The flexible container of claim **22** wherein the outside layer has a coefficient of friction of approximately 0.2 to about 0.4.

27. The flexible container of claim **22** wherein:

the outside layer has a thickness of approximately 40 to about 100 microns;

the inside layer has a thickness of approximately 40 to about 100 microns;

the gas barrier has a thickness of approximately 25 to about 50 microns; and

the core layer has a thickness of approximately 10 to 40 microns.

28. The flexible container of claim **27** wherein the outside and inside layer have approximately the same thickness.

29. The flexible container of claim **27** wherein each of the layers of urethane adhesive have a thickness of approximately 1 to about 10 microns.

30. The flexible container of claim **28** wherein the layers are bonded to each other at a peel strength of at least 500 gms/inch of force to delaminate.

31. The flexible container of claim **22** including a fitment heat sealed to the outside layer.

32. The flexible container of claim **22** wherein a portion of the inside layer is heat sealed together to create the walls of the flexible container.

33. The flexible container of claim **1** wherein the biaxially oriented nylon includes a slip agent.

34. The flexible container of claim **22** wherein the gas barrier layer is constructed from SARAN.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,692,361

DATED : September 8, 1987

INVENTOR(S) : William D. Johnston, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Front page, first column:

Assignees: Fujimori Kogyo Co., Inc., Tokyo, Japan, and Baxter Travenol Laboratories, Inc., Deerfield, Illinois

On the front page, add to the list of U.S. patent documents Under References Cited, the following entry:

3,912,843	10/1975	Brazier	428/474

Signed and Sealed this

Fifth Day of April, 1988

Attest:

Attesting Officer

DONALD J. QUIGG

Commissioner of Patents and Trademarks

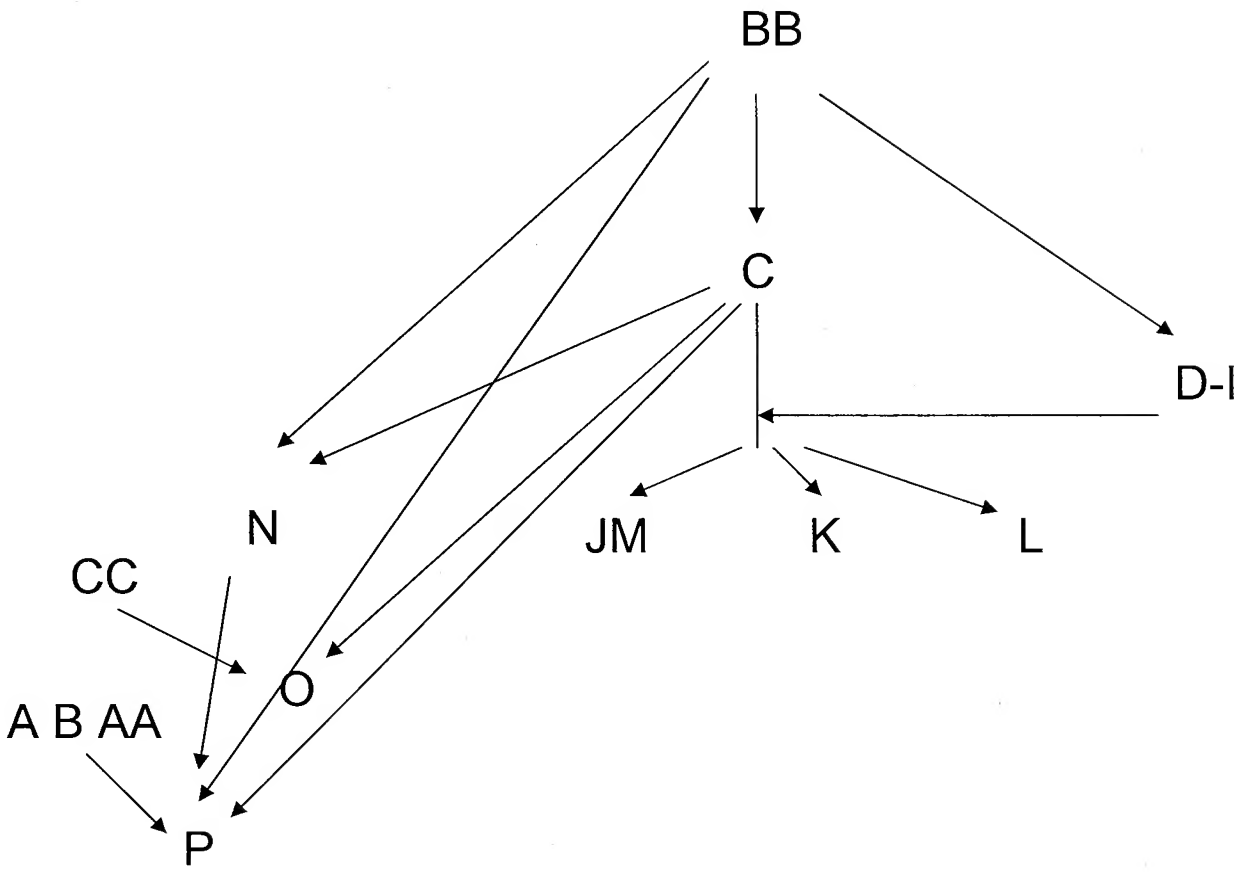

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EXHIBIT D

United States Patent [19]

Bacehowski et al.

[11] **Patent Number: 4,910,147**

[45] **Date of Patent: Mar. 20, 1990**

[54] **CELL CULTURE MEDIA FLEXIBLE CONTAINER**

[75] Inventors: **David V. Bacehowski**, Wildwood; **Arnold C. Bilstad**, Deerfield; **David Fisher**, Antioch; **Robert Gliniecki**, Richmond; **Michael R. Keilman**, Diamond Lake; **Sidney T. Smith**, Lake Forest, all of Ill.

[73] Assignee: **Baxter International Inc.**, Deerfield, Ill.

[21] Appl. No.: **247,463**

[22] Filed: **Sep. 21, 1988**

[51] **Int. Cl.**[4] **C12M 3/00**

[52] **U.S. Cl.** **435/296**; 435/284; 435/287; 435/286; 206/219; 206/484; 604/408; 215/247; 141/10

[58] **Field of Search** ..... 435/287, 296, 284, 286; 215/247, 365, DIG. 3; 604/403, 408, 409; 206/484, 484.1, 484.2; 141/10

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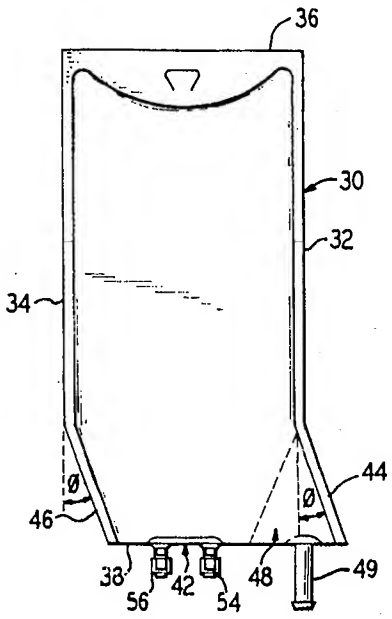
Primary Examiner—Larry Jones

Attorney, Agent, or Firm—Paul C. Flattery; Robert M. Barrett; Bradford R. L. Price

[57] **ABSTRACT**

A cell culture media container is provided. The container comprises a body constructed from flexible film and defining a containment area for containing the cell culture media, the body including a front face and a back face, the front and back face being sealed to each other along at least three sides thereof. The container includes a fill port for filling the containment area with cell culture media, the port being sealed to a face of the body and being so constructed and arranged that it extends from the face normal thereto. The container is constructed from a high barrier, optically clear, radiation sterilizable film.

24 Claims, 2 Drawing Sheets



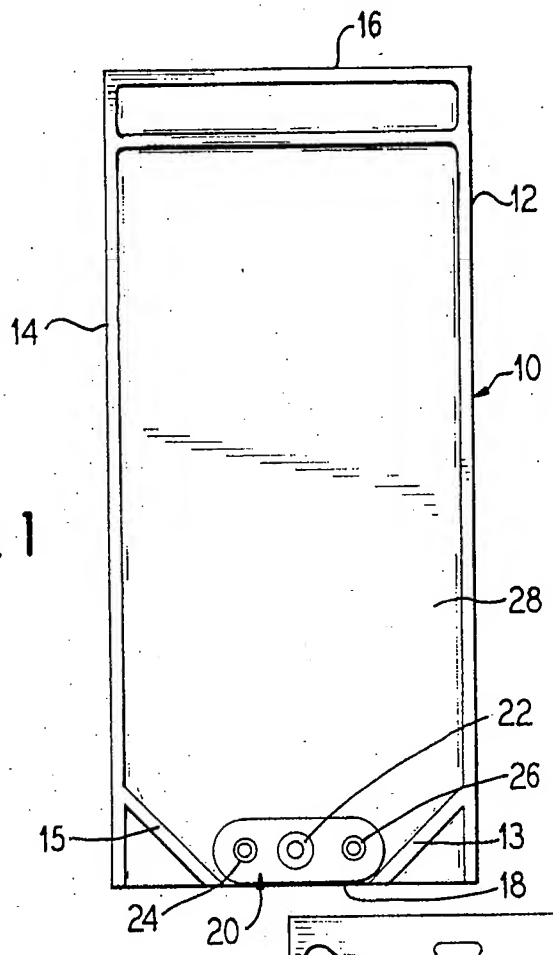


FIG. 1

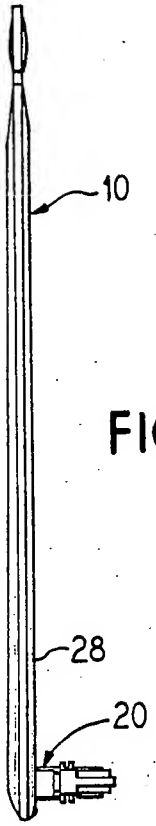


FIG. 2

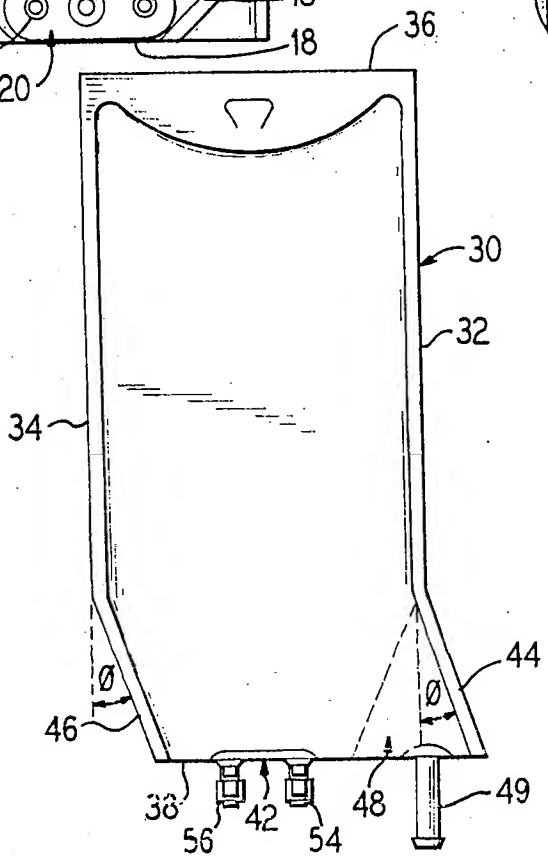


FIG. 3

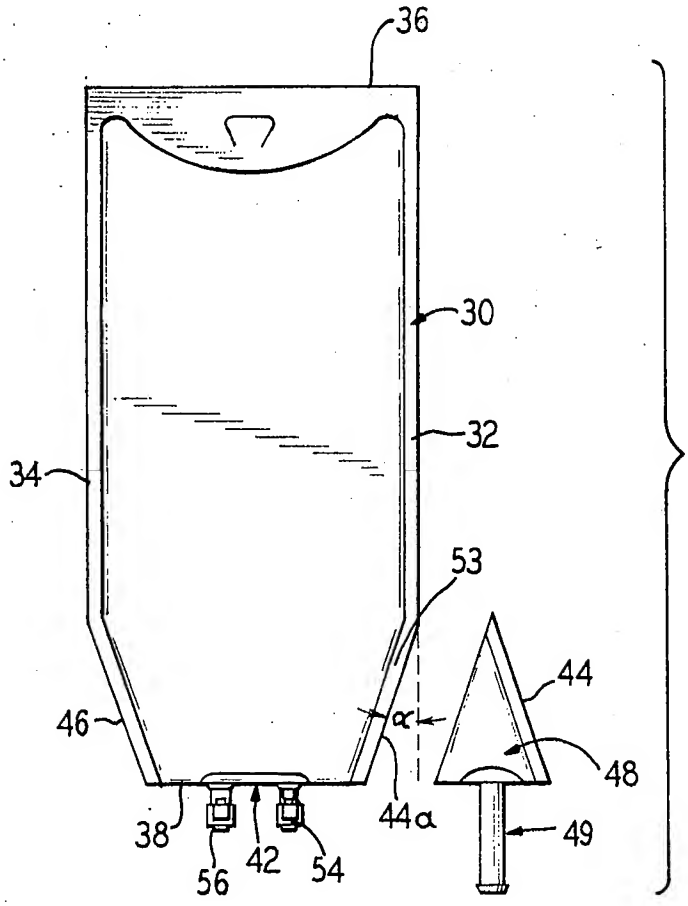


FIG. 4

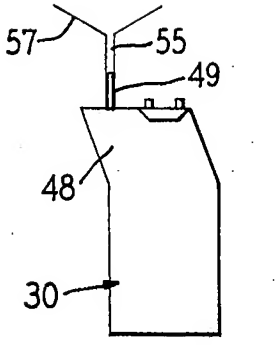


FIG. 5a

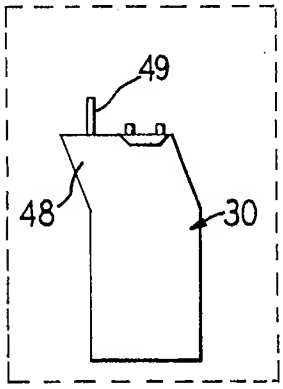


FIG. 5b

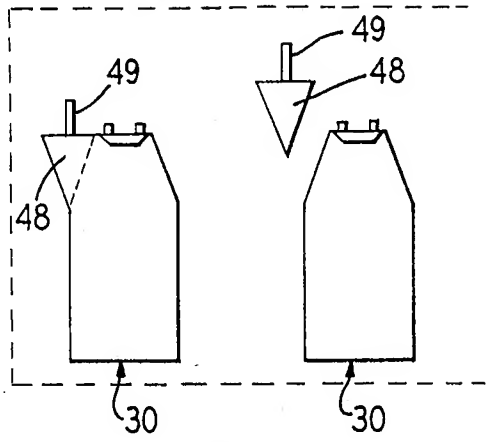


FIG. 5c

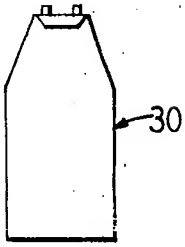


FIG. 5d

CELL CULTURE MEDIA FLEXIBLE CONTAINER

BACKGROUND OF THE INVENTION

The present invention relates, in general, to flexible containers. More specifically, the present invention relates to containers for containing cell culture media and other sensitive fluids.

Cell culture media is typically a solution of amino acids, electrolytes, and vitamins. Usually, the solution is supplemented with fetal bovine serum, which is believed to contain growth factors and other proteins that are essential to mammalian cell growth, without containing antibodies. Media is typically sold in either a liquid or powder form. If the media is sold in a powder form, it must be reconstituted prior to use.

Typically, liquid cell culture media is packaged in glass bottles, or containers, and stored at temperatures of approximately 2 to about 4° C. Glass bottles are used to package the cell culture media because of their barrier properties. Because amino acids are readily oxidized an oxygen barrier is needed. Furthermore, a carbon dioxide barrier is needed because typically a bicarbonate buffer system is used in the media. Moreover, it is critical that the interior surface of the container is inert because of the sensitivities of the cells to toxic leachables.

Cell culture media powder has been packaged in foil pouches or polyethylene bottles having screw caps. However, due to the structure of the pouches and/or bottles upon reconstitution the media must be placed in glass bottles. One of the disadvantages of powder media is that reconstituting the media and maintaining asepsis is labor intensive.

A typical "life cycle" for a glass bottle for containing cell culture media is as follows. The bottles are typically received from a glass manufacturer in bulk and inventoried by the media manufacturer. When needed, the bottles are unpacked, washed, and sterilized. The sterile bottles are then placed in a fill room where they are filled and capped. The filled bottles are conveyed from the fill room and inspected and labelled. The labelled bottles are placed in quarantine during testing of the product. Once a lot is released, the bottles are typically shipped to customers in specially designed corrugated cardboard containers. Customers must then unpack the bottles and store them in a refrigeration unit until use. When the bottles are used, they are uncapped using aseptic techniques and the media is removed by pouring it into another vessel or by pipetting. The glass bottle must then be disposed.

As illustrated above, the process of utilizing glass bottles for containing cell culture media has some clear disadvantages. Of course, the storage of glass bottles utilizes a large amount of warehouse space. This is not only a concern prior to the filling of the bottles with media but even after the bottles are filled The packaging density of glass bottles increases the warehouse space required in quarantine and release product.

Furthermore, the glass bottles are not presterilized and nonpyrogenic, therefore, prior to use, the bottles must be washed and sterilized. Moreover, due to the nature of glass, there is a possibility that the bottles will break or be damaged during shipping and handling.

Additionally, the typical techniques of removing the media from the glass bottles are time consuming and have a risk of contamination. Still a further disadvantage in using glass bottles is that there is a problem of disposing of the container after it has been emptied. An additional disadvantage of using a glass bottle is the cost associated with the handling of and the pre-filling processing of the containers.

Accordingly, there is a need for an improved container for containing cell culture media.

SUMMARY OF THE INVENTION

The present invention provides a cell culture media container comprising a body constructed from a flexible film that defines a containment area for containing the cell culture media. The body includes a front face and a back face. The front and back face are sealed to each other along at least three sides thereof. A fill port is provided for aseptically filling the containment area with cell culture media. The fill port is sealed to a face of the body and so constructed and arranged that it extends from the face, normal thereto.

The fill port can of course be filled in a nonaseptic manner in those applications where an aseptic condition is not required for the product to be housed in the container.

Preferably, the film is constructed from a high gas and water vapor barrier, optically clear, radiation sterilizable film. In an embodiment, the film is a laminate. In a further embodiment, the film is a polyolefin material. In a still further embodiment, the film is constructed from an inner layer of a polyethylene material, a core layer of a barrier material, and an outer layer of a polyolefin or polyester—based material.

Preferably, the port is constructed from a material that can be molded, has low gas permeability, and can be sonically welded. In an embodiment, the port is constructed from a polyolefin. In a preferred embodiment, the port is constructed from a polyethylene.

In a preferred embodiment, a container for housing a product constructed from a web of film and including an at least partially extending fill portion is provided. The container includes a top edge, a bottom edge, and side edges. The container is constructed so that portions of the side edges do not extend substantially normal to the top edge of the film. The fill segment is defined, in part, by a side edge portion of the container that extends from a remaining side edge portion of the container at an angle θ of greater than O° . The fill segment is designed to be, during the filling process of the container, sealed along a perimeter thereof from remaining portions of the container and severed therefrom. The fill port is secured to a portion of the fill segment.

A method for storing a product in a flexible container is also provided. The method comprises the steps of filling a fill port of a flexible container constructed from a web of film with a product, sealing a portion of the flexible container to define two sealed portions of the container, and severing the fill port and one of the sealed portions of the container from remaining portions of the container.

An advantage of the present invention is that it provides an improved cell culture media container.

A further advantage of the present invention is that it provides a cell culture media container having a port so constructed and arranged as to expedite the aseptic filling of the container with cell culture media.

A still further advantage of the present invention is that it provides a container that can be utilized with a semi-automatic aseptic fill machine.

Still, an advantage of the present invention is that it provides a fill port that is easily sealed to provide a sterile containment area.

Another advantage of the present invention is that the product is easily disposed of after a single use.

A further advantage of the present invention is that the design minimizes the potential for contamination by readily accommodating non-vented, aseptic solution transfer.

Another advantage of the present invention is that it provides a cell culture media container that can be stored in a minimal amount of space.

Another advantage of the present invention is that it provides a cell culture media container that, even when filled, requires a fraction of the space occupied by a typical glass container.

Additionally, an advantage of the present invention is that it provides a novel container construction.

A further advantage of the present invention is to provide an improved method for filling a container.

Additional features and advantages of the present invention will be apparent from the detailed description of the presently preferred embodiments and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a perspective view of an embodiment of a container for cell culture media of the present invention.

FIG. **2** illustrates a side elevational view of the container of FIG. **1**.

FIG. **3** illustrates a perspective view of another embodiment of a container for cell culture media of the present invention.

FIG. **4** illustrates a perspective view of the container of FIG. **3** after the fill portion of the container has been severed.

FIGS. **5***a*, **5***b*, **5***c* and **5***d* schematically illustrate the steps in a method of filling the container of FIG. **3**.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention provides a flexible, high barrier container for cell culture media and other sensitive fluids. The container is constructed for aseptic fill applications. The container includes the following characteristics: radiation resistance; sterile, non-pyrogenic; shatterproof; nonvented; has an inert, nonreactive interior surface; high gas barrier properties; high moisture barrier properties; and high strength and flex-crack resistance properties.

Preferably, the container has an integrally attached high barrier fill port that is designed to interface with a semi-automatic, aseptic fill machine, especially the nozzle thereof. The container offers numerous advantages over typical glass cell culture media containers. To this end, the container in a nonfilled, collapsed condition, requires only a fraction of the space required by typical glass containers. Furthermore, the flexible container can be presterilized and is nonpyrogenic eliminating the need for washing and sterilization by the user. Moreover, the flexible containers, even when filled with product, have a higher packaging density than typical glass bottles thereby reducing the warehouse space required for the product in quarantine and release product. Also, the shatterproof nature of the flexible container substantially reduces breakage during shipping and handling.

Referring now to FIG. **1**, a flexible container for housing cell culture media **10** is illustrated. The container includes sides **12** and **14**, a top edge **16**, and a bottom edge **18**. The container **10** is constructed from a web of film that is folded along the edge **18** and sealed along edges **12**, **14**, and **16**. Preferably, the web of film includes at least one thermal heat sealable layer allowing the edges of the web of film to be heat-sealed together.

In the embodiment of the container **10** illustrated, the container includes chevron seals **13** and **15**. The chevron seals **13** and **15** improve the delivery characteristics of the container **10**.

Preferably, the web of film from which the container is constructed has the following properties. It has very few to no leachables-extractables, and is therefore nonreactive with the solution to be housed therein. The film has high gas barrier properties and provides a good barrier to oxygen and carbon dioxide. The film possesses a low to nil water vapor transmission rate. The film has good clarity and therefore enables viewing of the contents. This is important in that it allows one to determine growth of contamination/pH indicator changes. Preferably, the film is able to withstand storage temperatures between ambient temperature to −80° C. Moreover, the film is able to withstand ambient shipping temperatures and conditions. Still, the film will allow the media to be warmed prior to use. Usually cell culture media is warmed by immersing the container in a water bath that is heated to 37° C.

Preferably, the film is constructed from a material that includes a polyolefin material. Preferably, the film also includes a high barrier material. Polyvinylidene chloride and ethyl-vinyl alcohol (EVOH) have been found to function satisfactorily as a barrier material. Preferably, the film is a laminate including an outer layer, an inner layer, and a core layer. A polyolefin material preferably defines the inner layer, a barrier material defines the core layer, and a polyolefin or polyester-based material defines the outer layer. In a preferred embodiment, the outer and inner layers are polyethylene based materials, i.e., they include at least a polyethylene in the composition. Preferably, the layers are bonded together with a radiation resistant, bicompatibile adhesive.

By way of example, and not limitation, a film that has been found to function satisfactorily as a cell culture media container will now be set forth. The film is a laminate having: an outer layer constructed from approximately 5%, by weight, ethyl-vinyl acetate and approximately 95%, by weight, low density polyethylene; a core layer constructed from biaxially oriented ethyl-vinyl alcohol (EVOH); and an inner layer constructed from linear low density polyethylene. The film has the following, approximate, layer thicknesses: the outer layer is approximately 0.002 inches thick; the core layer is approximately 0.0005 inches thick; and the inner layer is approximately 0.002 inches thick. Such a film is sold by Curwood, Inc. of New London, Wisconsin as 6520 laminated film.

This film has been found to provide an inner layer that meets the criteria previously stated and has good thermal bonding properties. The core layer provides a layer having good barrier properties, especially with respect to gas transmission, and the outer layer provides the film with good strength and flex crack resistance. In the embodiment of the film given in this example, the layers are sealed together by a polyester adhesive. Of

course, the above film is only presented by way of example and other components can be utilized for the film (as discussed previously), the film may include more or less than three layers, and the layers can have different thicknesses.

As illustrated in FIGS. 1 and 2, the container 10 includes a fitment 20. The fitment 20 provides means for accessing a containment area defined by the container for filling the container and/or accessing the contents of a filled container. To this end, in the embodiment illustrated in FIGS. 1 and 2, the fitment 20 includes a fill port 22 and access ports 24 and 26.

In constructing the container 10, in an embodiment, holes are punched in the film and the fill port 22 and access ports 24 and 26 are inserted therethrough and a top portion of the body of the fitment 20 is sealed to the film.

The fill port 22 is utilized to fill the container 10 with cell culture media. Preferably, the fill port 22 is constructed from a material that can be easily sealed. Accordingly, after the container 10 has been filled with cell culture media, the fill port 22 can be sealed enclosing the cell culture media within the container 10. In a preferred embodiment, the fill port 22 is constructed from a material that can be sonically welded. Preferably, the fill port 22 is constructed from a polyolefin. In an embodiment, the fill port 22 is constructed from a high density polyethylene.

Typically, in use, the container is filled by having a nozzle or other means inserted in the fill port and cell culture media fed therein. The nozzle or other means is then removed from the fill port and the fill port is sonically welded. This provides a container 1O, containing cell culture media, that is sealed.

As illustrated, the fitment 20 includes access ports 24 and 26. It should be noted that although two access ports are illustrated on the fitment 20, more or less access ports can be utilized. Furthermore, if desired, the fill port 22 and access ports 24 and 26 can be secured to separate fitments.

The access ports 24 and 26 provide a means for accessing the contents of the container 10. To this end, the access ports 24 and 26 are designed to receive a standard spike/luer. Preferably, the access ports 24 and 26 are sealed by a removable cap and include a pierceable membrane that is pierced by a spike, or like means, when the container is accessed. Of course, other means of accessing the container via the access ports 24 and 26 can be utilized.

As illustrated in FIGS. 1 and 2, in contrast to a standard fitment and port arrangement, the container 10 of the present invention is constructed so that the fitment 20, and specifically the ports 22, 24, and 26 extend outwardly from a face 28 of the container 10. In typical flexible containers, the fitment or ports extend from the bottom edge of the container in a plane that is substantially parallel to a plane defined by the face of the container. By extending the ports 22, 24, and 26 of the fitment 20 outwardly from the face 28 of the container 10, i.e., normal to a plane defined by the face 28 of the container 10, an improved container is provided in that it affords a container that can be easily and cost effectively fabricated and filled with cell culture media utilizing a semi-automatic, aseptic fill machine. Further, the fitment arrangement 20 provides a container 10 from which the cell culture media stored therein can be easily accessed.

Referring to FIG. 3, another embodiment of the container 30 of the present invention is illustrated. Again, the container 30 is constructed from a flexible web of film having the same characteristics as set forth above for the embodiment of the container 10 illustrated in FIGS. 1 and 2. Likewise, the container 30 can be constructed from the films discussed above with respect to the previous embodiment of the container 10.

Similar to the previous embodiment of the container, the web of film is folded along an edge 38 and sealed on sides 32 and 34 and a top edge 36. However, in contrast to the previous embodiment illustrated in FIGS. 1 and 2, the side edges 32 and 34 do not extend for a length of the container 30 perpendicularly or normal to the top edge 36 of the container 30. Instead, portions of the side edges 44 and 46 extend outwardly, and inwardly, from remaining sides edges 32 and 34, respectively, and therefore, do not extend perpendicularly from the top edge 36.

As illustrated, the side edge 44 extends outwardly from remaining portions of the side edge 32 at an angle 8 that is greater than O°. Preferably, the angle 8 is greater than O° . but less than 90° . The side edge portion 44 defines, with portions of the container 30, an at least partially extending fill segment 48. As discussed in more detail hereinafter, the fill segment 48 is utilized to fill the container with cell culture media and designed to be severed from the container 30 after the filling process. To this end, a fill port 49 is secured to the container 30 at a location in juxtaposition to the side edge portion 44 of the container 30.

As previously stated, a second side 34 of the container 30 includes a portion 46 that also does not extend along the container 30 perpendicularly to the top edge 36. In this regard, side edge portion 46 extends inwardly from the remaining side edge portions 34 at an angle ϕ. Angle ϕ is greater than O° but less than 90°.

Referring to FIG. 4, the container 30, after it has been filled through the fill port 49, is illustrated. As illustrated, the container 30 has been sealed along a perimeter 53 segregating the fill segment 48 from remaining portions of the container, and the fill segment has been severed from the container 30. In an embodiment, the fill segment 48 is severed from the container 30 by means that severs the fill segment while sealing the container. As illustrated, once so severed, the container 30 includes a side edge portion 44*a* that now extends from the remaining side portions 32 inwardly at an angle α that is greater than O° but less than 90°. The container 30 illustrated in FIG. 4 has been filled and accordingly now is in a condition where it can be accessed by the user through access ports 54 and 56 of the fitment 42.

Referring now to FIG. 5, a schematic illustrating a method of filling the container 30 of FIG. 3 is illustrated. As illustrated, in step 5*a*, the container 30 is filled through a fill port 49 by a nozzle 55 of an aseptic fill machine 57. In step 5*b*, the fill port 49 is then sealed by sonic welding or some other means. In step 5*c*, the container 30 is sealed along a perimeter of the fill segment 48 by thermal sealing means. After the container 30 is so sealed, the fill segment 48 is then cut by a die or some other means. It should be noted, however, that means for contemporaneously sealing and severing the fill segment 48 can be utilized. 5*d* illustrates the filled container 30 that can now be accessed when desired.

It should be understood that various changes and modifications to the presently preferred embodiments

described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

We claim:

1. A cell culture media container comprising:

a body constructed from flexible film that comprises an inner layer constructed from a polyethylene material, a core layer constructed from a barrier material, and an outer layer constructed from a material chosen from the group consisting of polyethylene and polyester-based material, the body defining a containment area for containing the cell culture media and including a front face and a back face, the front and back face being sealed to each other along at least three sides thereof; and

a fill port for receiving a nozzle means that fills the containment area with cell culture media, the port being sealed to a face of the body and being so constructed and arranged that it extends from the face normal thereto.

2. The cell culture media container of claim 1 wherein the film is a high barrier, optically clear, radiation sterilizable film.

3. The cell culture media container of claim 2 wherein the film is a laminate.

4. The cell culture media container of claim 1 wherein the fill port is constructed from a material that can be sonically welded.

5. The cell culture media container of claim 1 wherein the flexible film is constructed, at least in part, from a polyolefin.

6. The cell culture media container of claim 1 wherein the port is constructed from a moldable polyethylene.

7. A cell culture media container comprising:

a body, constructed from a web of film folded onto itself and sealed on at least three sides to define a containment area to be filled with a cell culture media, the web of film comprising an inner layer constructed from a polyethylene material, a core layer constructed from a barrier layer, and an outer layer constructed from a material chosen from the group consisting of polyethylene and polyester-based material, the body including, prior to being filled with the cell culture media, two faces that lie in substantially parallel planes; and

at least one port providing means for filling the containment area with cell culture media, the port being secured to a face of the body and extending outwardly therefrom normal to at least one plane defined by the faces of the body.

8. The cell culture media container of claim 7 wherein the fitment is constructed from a high density polyethylene.

9. The cell culture media container of claim 7 wherein the fitment is secured to the face of the body by having portions thereof being received within a hole punched in the web of film, and portions thereof extending outwardly from the hole.

10. The cell culture media container of claim 7 wherein the body includes at least one chevron seal for sealing a portion of the first face to a portion of the second face.

11. The cell culture media container of claim 7 wherein the barrier layer is constructed from a material chosen from the group consisting of polyvinylidene chloride and ethyl-vinyl alcohol.

12. The cell culture media container of claim 7 wherein the film includes an outer layer constructed from 5%, by weight, ethyl-vinyl acetate and 95%, by weight, polyethylene, a core layer constructed from ethyl-vinyl alcohol, and an inner layer constructed from polyethylene.

13. The cell culture media container of claim 12 wherein the film is a laminate and the layers are secured together by a polyester adhesive.

14. The cell culture media container of claim 7 including a second access port for accessing the contents of the containment area.

15. A container for housing product, the container constructed from a web of flexible film and comprising:

a top edge, a bottom edge, and side edges, each of the side edges having a greater length than a length of either of the top edge or bottom edge and the side edges including portions thereof that do not extend perpendicular to the top edge, one portion of one of the side edges extending outwardly from a remaining portion of the edge at an angle θ that is greater than 0°, the container including a fill port.

16. The container of claim 15 wherein the portion of the side edge that extends outwardly defines, with portions of the body, a fill segment of the container, the fill port being secured to the fill segment of the container.

17. The container of claim 16 including an access port secured to the container at a location other than the fill amount of the container.

18. The container of claim 15 wherein one portion of one of the side edges extends inwardly from remaining portions of the side edge at an angle ϕ that is greater than 0° and less than 90°.

19. A method for storing a fluid in a flexible container comprising the steps of:

at least partially filling a flexible container constructed from a web of film with a fluid, by feeding fluid into the container through a fill port in the container;

sealing a portion of the flexible container to define two sealed portions, one of the portions including the fill port; and

severing the sealed portion of the container having the fill port from remaining portions of the container.

20. The method of claim 19 including the step of sealing the fill port before sealing the portion of the container.

21. The product of the process of claim 20.

22. The method of claim 19 including the step of contemporaneously sealing and severing a portion of the bag.

23. The product of the process of claim 19.

24. A container for housing product made in accordance with the method of claim 19, the container constructed from a web of flexible film and further including a top-edge, a bottom edge, side edges, and a fill port.

* * * * *

EXHIBIT E

United States Patent [19]

Bell et al.

[11] **Patent Number: 4,936,456**

[45] **Date of Patent: Jun. 26, 1990**

[54] **BAG ARRANGEMENT**

[75] Inventors: **Gary M. Bell**, Crystal, Minn.; **Cecil E. Richison**, Hudson, Wis.; **Paul W. Gazillo**, Roselle, Ill.

[73] Assignee: **Kapak Corporation**, St. Louis Park, Minn.

[21] Appl. No.: **334,786**

[22] Filed: **Apr. 6, 1989**

Related U.S. Application Data

[63] Continuation of Ser. No. 180,527, Apr. 12, 1988, abandoned.

[51] **Int. Cl.**[5] **B65D 33/01**

[52] **U.S. Cl.** **206/439**; 206/631; 206/632; 206/633; 206/484.1; 383/102; 383/120

[58] **Field of Search** 383/78, 93, 94, 102, 383/120; 206/610, 613, 631, 632, 633, 439, 484.1

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Primary Examiner—Stephen Marcus

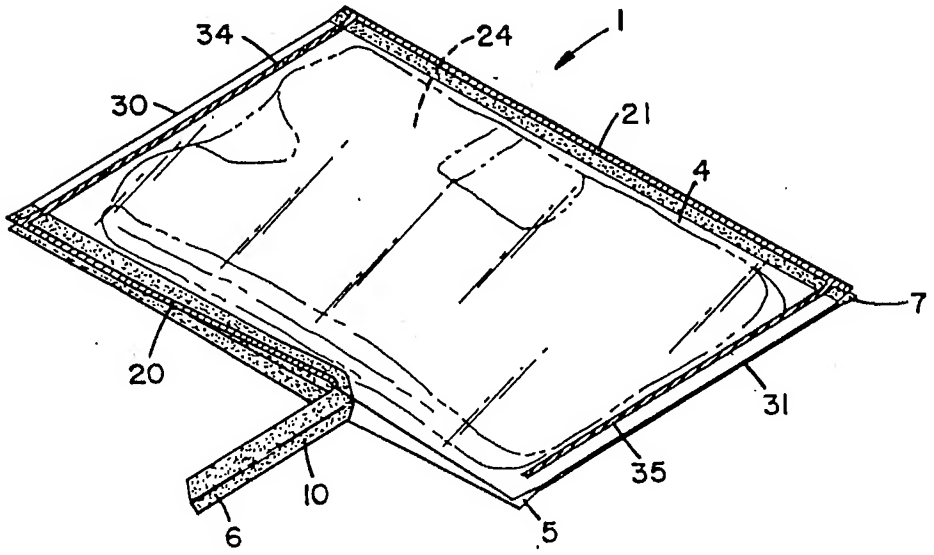
Assistant Examiner—Jes F. Pascua

Attorney, Agent, or Firm—Merchant, Gould, Smith, Edell, Welter & Schmidt

[57] **ABSTRACT**

A bag construction is provided. In the preferred embodiment, the bag construction or arrangement comprises first and second side panels, and first and second edge gusset members. The gusset members are peelable from between the side panels; peeling being facilitated by positioning of end tab extensions at both ends of each gusset member. In a preferred embodiment, both side gusset members comprise a gas-permeable material of sufficient density to act as a contaminant filter, so that contents within the bag arrangement can be sterilized by a gas sterilization procedure.

29 Claims, 2 Drawing Sheets



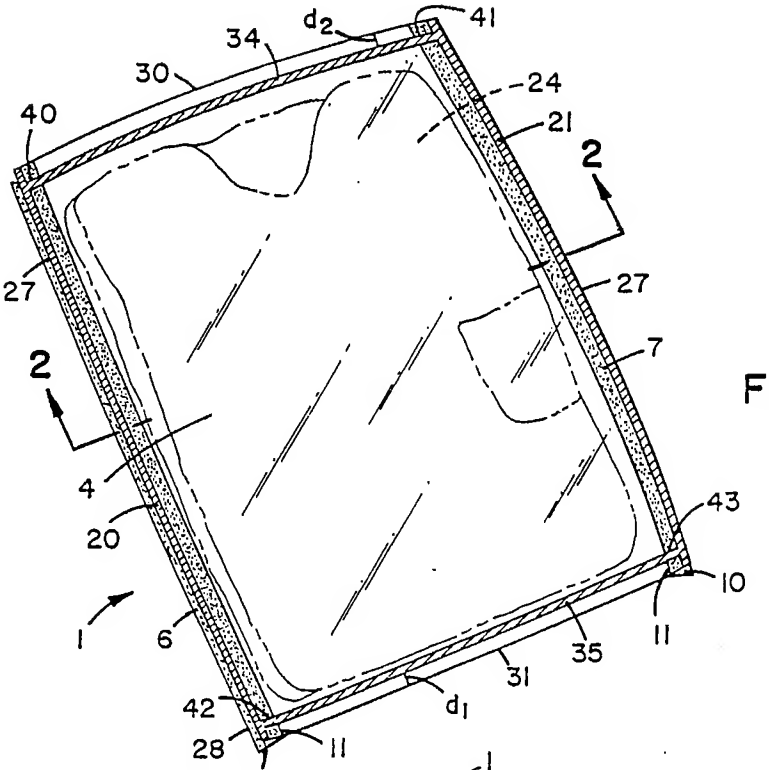


FIG. 1

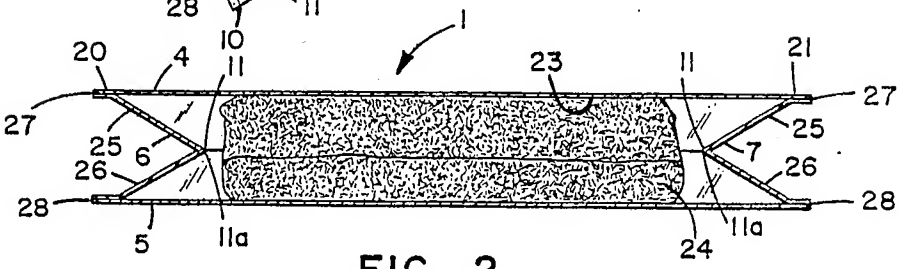


FIG. 2

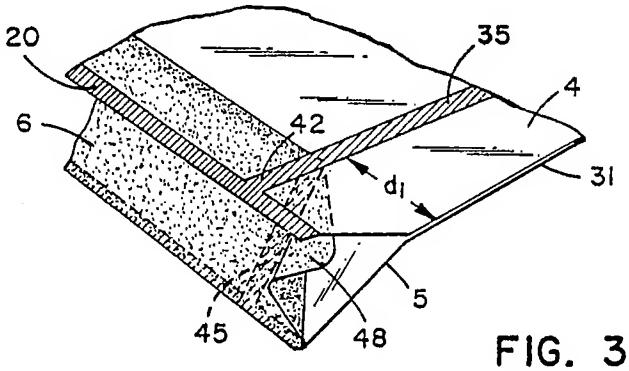


FIG. 3

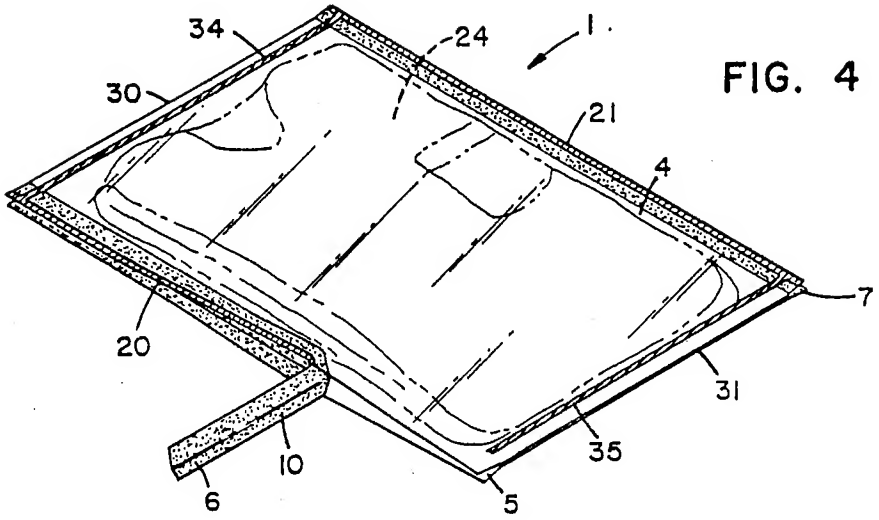


FIG. 4

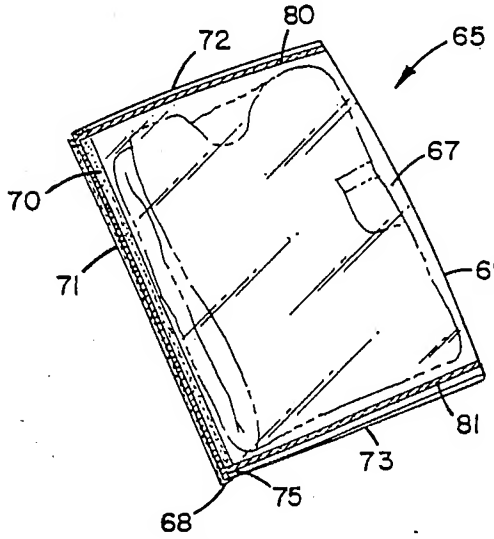


FIG. 5

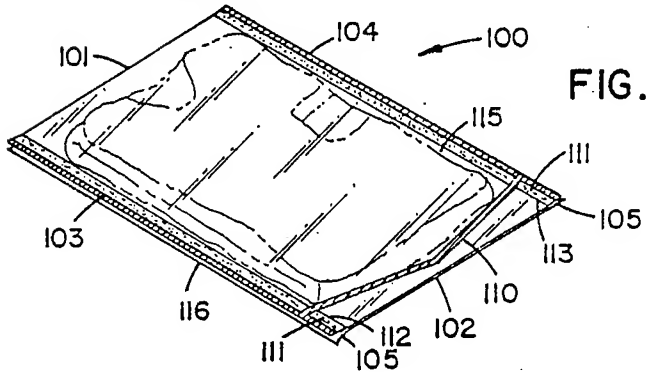


FIG. 6

BAG ARRANGEMENT

This is a continuation-in-part continuation, of application Ser. No. 07/180,527, filed 4/12/88 now abandoned.

FIELD OF THE INVENTION

The present invention relates to bags, sacks or pouches. For a preferred embodiment, the invention concerns a high-profile, sterilizable, bag arrangement having features providing for ease of opening.

BACKGROUND OF THE INVENTION

A very wide variety of bag and/or pouch constructions are well-known, for a variety of uses. The present invention particularly concerns bags or pouches used for the containment of articles or products. For example, a consumer product may be distributed and/or sold in a protective bag according to the present invention.

Such bags or pouches are conventionally sealed in a variety of manners, including with heat sealing, adhesives, mechanical fasteners and similar arrangements. Preferred embodiments of the present invention particularly concern pouches which are heat sealed, although other sealing methods may be used in embodiments involving the principles of the invention.

For many applications it is desirable to maintain an enclosed article substantially sterilized, prior to use. In some instances, items must be sterilized with heat, prior to being sealed within a pouch or the like. While this method of sterilization is effective for some uses, for many it is inappropriate. Reasons for this include: costs; potential damage to certain products or packages from sterilizing heat; and, inconvenience, especially with mass-manufacture processes.

It is also known that sterilization can be effected through the utilization of gas treatments such as with ethylene oxide. In a typical application, a pouch including a gas-permeable wall section is prepared, and the item to be sterilized is placed within the bag. The bag is then sealed. The sealed bag is placed in an ethylene oxide environment. The ethylene oxide can permeate the gas-permeable wall section, sterilizing the inside of the bag and products enclosed therein. If an appropriate gas-permeable material is selected, then bacteria cannot readily pass through the wall section, to re-contaminate the inside of the bag and/or products contained therein. That is, the gas-permeable material acts as a filter. As a result, the sealed product can be stored in a non-ethylene oxide environment, for a substantial period of time, without substantial contamination of the enclosed item.

A variety of pouch constructions have been developed which include gas-permeable wall sections therein, for gaseous sterilization. In some such systems, generally one end or edge of the bag comprises a "header" of the gas-permeable material. Such conventional arrangements have generally not been fully acceptable for numerous reasons. First, the arrangements using them have been relatively expensive to construct. Secondly, substantially complete equilibria within the bag, to obtain ethylene oxide penetration throughout substantially all portions of the bag and the enclosed items, has been slow to develop. Also, conventional pouch structures have not readily accommodated high-profile items, i.e. items which have a substantial thickness and require a bag to expand a considerable amount to be fit therearound.

A variety of materials can be utilized as the gas-permeable wall section. In general, what is required is a material: sufficiently strong and pliable for use as a portion of a pouch or the like; sufficiently permeable to gas; and, which acts as a filter to prevent passage of recontaminating bacteria or the like therethrough. Spunbonded high density polymeric (esp. polyethylene or polypropylene) materials, such as TYVEK (Dupont) are particularly well adapted for such uses.

Numerous other features are desirable in bag or pouch constructions, for certain applications. Some of these relate to, or concern, the following:

1. For some applications it is desirable that the pouch be expandable, to accommodate products of a variety of profiles. That is, it is desirable that the bag be such as can be easily expanded, and retained opened to receive an item or items therein. Some conventional arrangements, utilizing side gussets, have been developed to accommodate this. In general, these side gussets have been formed in bags of unitary structure, having a single seam therein. The seam, in general, has been placed along a side edge or back portion of the bag. The side gussets generally comprise an inward > or < shaped gusset in the sides of the pouch. Such gussets can act as a hinge, allowing front and back panels of the pouch to be collapsed toward or away from one another, in an accordion-like fashion. As a result of such arrangements, high-profile items can be easily stored within the bag.

2. In many instances, it is desirable that sealed bags, having products stored therein, include means facilitating easy opening. A variety of structures to accommodate these have been developed, including tear lines and notches.

As previously indicated, a very wide variety of bag or pouch designs have been developed. Many of these designs are well-suited for a variety of applications. However, improved designs have been needed to better accommodate: features for easy expandability to accommodate high-profile items stored therein; features facilitating easy opening; and, features facilitating utilization of a variety of materials, such as gas-permeable materials, for side panel members especially when such materials differ from the materials utilized for front and back panels in the pouch.

OBJECTS OF THE INVENTION

Therefore, the objects of the present invention include: the provision of a bag or pouch construction utilizing at least one and preferably two accordion-like side gusset members constructed from material which is not unitary with front and back panels of the pouch; to provide a preferred such arrangement wherein at least one side gusset member comprises a gas-permeable material utilizable to facilitate a sterilization process for materials stored within the pouch; to provide a preferred such arrangement having two opposite gusset members both of which comprise a gas-permeable material; to provide a preferred arrangement, for a pouch having accordion-like side gusset members, which includes means facilitating ease of opening; to provide a preferred pouch construction having gas-permeable, accordion-like, side gusset members for sterilization, and including means facilitating ease of opening; and, to provide such a preferred pouch construction which is relatively easy and relatively inexpensive to effect, and which is particularly well-adapted for the proposed usages thereof.

Other objects and advantages of the present invention will become apparent from the following descriptions, taken in connection with the accompanying drawings, wherein are set forth by way of illustration and example various embodiments of the present invention.

SUMMARY OF THE INVENTION

A pouch or bag construction is provided with a side panel arrangement which includes front and back panels, and at least one and preferably two, opposite, side gusset members. At least one, and preferably both, of the side gusset members is constructed non-integral (i.e. non-unitary) with the front and back panels. That is, at least one, and preferably both, of the side gusset members comprises a piece of material independent of the front and back panels, and attached to the front and back panels by means of a heat seal, adhesive or the like. Preferably the side gusset members have elongate, inwardly directed, hinge folds, to facilitate expansion of the bag, in an accordion-like manner, to accommodate the storage or containment of highprofile items therein.

As a result of the material utilized for the side gusset(s) being non-integral with the front and back panels of the pouch or bag construction, a number of advantages are provided. For example, the side gusset(s) may be constructed from a different type of material then are the front and back panels. Also, means facilitating easy opening of the bag construction, are provided.

There are a number of reasons why it might be desirable to have a side gusset construction such that the side gusset(s) can be made from a different piece of material than the front and back panels of the bag. For example, decorative strips, printed in a manner different than the front and back panels, can be readily utilized. A particular advantage of bag constructions according to the present invention is that the side gusset may be constructed from a material such as TYVEK (DuPont), i.e., a gas-permeable material resistant to bacteria (contaminant) passage therethrough. As a result of side gusset construction from such a material, pouches or bags according to the present invention are particularly well suited for utilization to store items therein that are to be kept sterile; for example, hospital gowns and equipment such as catheters, etc. If a relatively stiff material is used for side gussets, means are provided which help keep the bag held open.

The expandable side gusset construction of the preferred embodiment not only facilitates introduction of gas-permeable material therein, for use in sterilization processes, but it also facilitates the sterilization process itself. A reason for this is that it allows the bag to be opened or expanded considerably facilitating good, efficient, permeation by the sterilizing gas, for example ethylene oxide. In a preferred construction, oppositely located gas-permeable gusset members are positioned within the bag construction to facilitate rapid permeation of the sterilizing gas to substantially all portions of the internal volume.

Bag constructions according to the present invention include means facilitating ease of opening. In particular, since at least one of the side gusset members is non-integral (i.e. non-unitary) with the front and back panels between which it is mounted, the pouch can be opened by stripping or removal of this gusset member. This is facilitated by two features comprising: a grab-tab or pull-tab arrangement or extension facilitating gripping of the side gusset, to strip same from its position in the unopened bag or pouch, i.e. from between the front and back panels; and, use of a release coat material in association with seams, typically on the side gusset(s) to facilitate stripping from sealing association with the front and back panels. These features will be further understood by reference to the detailed description below.

Preferred bag or pouch constructions according to the present invention comprise: front and back panels of material(s), such as plastic material, which is heat sealable; elongate side gusset members having an internally directed hinge fold therein; edge-to-edge heat seals or seam arrangements directed between opposite side gusset members, and generally enclosing ends of the bag construction by sealing the front and back panels to one another; elongate side edge seals or seam arrangements extending along four edges of the bag construction, each edge being a seam whereat a side gusset member is attached to one or the other of the front and back panels; release coat means associated with each seal between a side gusset member and a front or back panel; and, a pull-tab arrangement or extension whereby a side gusset member can be easily grabbed or gripped for stripping from the bag construction. As will be understood from the detailed descriptions, especially upon comparison of the various embodiments depicted, the edge-to-edge seals need not be linear and they need not be perpendicular to the gusset members.

The drawings constitute a part of this specification and include exemplary embodiments of the present invention, while illustrating various objects and features thereof. It will be understood that in some instances relative component sizes and material thicknesses may be shown exaggerated, in order to facilitate an understanding of the invention and to clarify the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a bag construction according to the present invention shown sealed closed with a relatively high-profile article received therein.

FIG. 2 is a cross-sectional view taken generally along line 2—2, FIG. 1.

FIG. 3 is an enlarged fragmentary perspective view of a corner portion of the arrangement shown in FIG. 1.

FIG. 4 is a perspective view of an arrangement according to the invention as illustrated in FIG. 1, shown partially opened.

FIG. 5 is a perspective view of a bag or pouch construction according to a first alternate embodiment of the present invention.

FIG. 6 is a perspective view of a bag or pouch construction according to a second alternate embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

As required, detailed embodiments of the present invention are disclosed herein. It is to be understood, however, that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but rather as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed system or structure.

The reference numeral 1, FIG. 1, generally designates a bag or pouch arrangement or construction according to the present invention. As used herein, the terms "bag", "pouch" and variants thereof are meant to

refer to a flexible enclosure arrangement, i.e., a sack-like arrangement inside of which an article may be enclosed. Typically, bags or pouches according to the present invention are utilized for the storage and protection of consumer items. That is, items of interest are sealed within the bag or pouch, during a packaging operation, and are then shipped to distributors, wholesalers, retailers, consumers, etc. When desired, the bags are torn open to gain access to items received therein.

The bag remnants, following opening, are generally to be disposed of, rather than recycled or reused. Thus, designs which are relatively inexpensive to effect are preferred.

Referring to FIG. 2, bag 1 comprises first and second opposite sides of panels 4 and 5, and first and second opposite side gussets 6 and 7. Panels 4 and 5 generally comprise front and back panels of bag 1. The panels can be formed from a variety of materials, including paper, polymeric films or the like. The panels 4 and 5: can include advertising or decorative indicia thereon; they may be colored; and, they may be formed from transparent, translucent, opaque or non-light transmissive materials. There is no requirement that panels 4 and 5 be constructed from the same material. It is foreseen that in typical applications, panels 4 and 5 will comprise a conventional, heat-sealable, substantially transparent plastic material such as a polyethylene or polypropylene plastic. Such materials are conventionally utilized for storage bags; they are readily available from a variety of sources; they are relatively inexpensive; and, they are easily handled.

Many of the advantages of the present invention are derived from the following features: the shape of the side gusset members 6 and 7; the fact that at least one, and preferably both, of the side gusset members 6 is 7 are non-integral (i.e. non-unitary) with both of panels 4 and 5; and, the nature of the seals among the panels 4 and 5, and the gussets 6 and 7. For a preferred embodiment, certain advantages are obtained from the particular material chosen for construction of the side gussets 6 and 7. Details concerning these features, and the advantages derived therefrom, will be apparent from the following.

Referring to FIGS. 1 and 2, each of side gussets 6 and 7 comprises an elongate strip 10 of material. Each includes a longitudinal, substantially centrally disposed, hinge fold 11. Referring to FIG. 1, the strips 10 are positioned between panels 4 and 5 to extend along opposite side edges 20 and 21 of the bag 1, with hinge folds 11 defining central hinge lines 11*a* generally directed inwardly of the bag 1. That is, referring to FIG. 2, the hinge folds 11 are directed toward an interior 23 of the bag 1, wherein for typical use an article 24 is located. The hinge-folds of each extension define a pair of flaps or gusset panels 25 and 26.

Referring to FIGS. 1 and 2, each gusset 6 and 7 is sealed between opposite panels 4 and 5, along seal or seam lines 27 and 28, preferably by means of a preferred seam arrangement as described.

A variety of edge seam arrangements seal or seam types may be utilized along lines 27 and 28. For typical applications, a heat seal or adhesive seal will be used, most preferably a heat seal. Heat seals can be easily produced; they are not messy to create; and, they are relatively sturdy.

Also, preferably seals or seams 27 and 28 are peelable. That is, under an appropriate tearing stress, the materials joined at seams 27 and 28 can be readily stripped apart from one another. Conventional "peelable" seals or seams are well-known, and can be achieved in a variety of manners. Typically, they are accomplished by providing one or both of the materials joined at the seam with a release coat thereon. A variety of conventional release coats are known and materials having them are commercially available. Preferably, all that is required to obtain advantages according to the present invention is that the seals 27 and 28 be such that they can be peeled by human hand, without excessive force, and that they otherwise be operable to provide a good environmental seal for protection of article 24 stored within bag 1. The term "peelable" and variants thereof, as used herein, is meant to refer to a seam readily openable upon application of such force such as may be readily applied by a person of about ordinary strength.

Referring to FIG. 1, bag 1 includes opposite ends 30 and 31. Generally, at ends 30 and 31, FIGS. 1 and 3, opposite panels 4 and 5 abut one another. Panels 4 and 5 are joined to one another along end seam arrangements end seams or seals 34 and 35. A variety of methods of providing for seals 34 and 35 may be utilized. It is foreseen that for typical, preferred, embodiments seals 34 and 35 will be heat seals, which again are relatively inexpensive to obtain and are relatively sturdy in construction.

Referring again to FIG. 1, it is noted that in corner sections of the bag construction 1, seals 34 and 35 each include four extensions, whereat they extend into conjunction with gusset panels 25 and 26 of the side gussets 6 and 7. In particular, FIG. 1, for panel 4, seal 34 includes two upper extensions 40 and 41, and seal 35 includes two upper extensions 42 and 43. Lower extensions are not viewable in FIG. 1, but will be understood to be analogous to the upper extensions. Extension 42 is more clearly viewable, in the fragmentary perspective view of FIG. 3. From FIG. 3 it will be understood that each extension, for example extension 42, comprises a point of sealing or bonding in the direction of the associated seal, (seal 35 in FIG. 3), between the side gusset (6) and the associated panel, (panel 4 in FIG. 3). In FIG. 3 a lower extension 45, comprising the analogue to extension 42 is shown in phantom lines. It will be understood that for the embodiment of FIGS. 1 and 3 each upper extension 40, 41, 42 and 43 has an analogous lower extension.

As a result of the edge seals 27 and 28, the end seals 34 and 35, and the seal extensions (upper extensions 40, 41, 42 and 43 and their analogues), an article 24 enclosed within bag construction 1 is sealed therein.

It is noted that while seals 34 and 35 between panels 4 and 5 could be made peelable, for the embodiment shown in FIG. 1 no particular advantage would be obtained therefrom. That is, it is desirable to be able to strip the side gussets 6 and 7 in order to open the bag 1, but there is no particular need, for many uses, to be able to easily strip panel 4 from panel 5. It is also noted that if strips 6 and 7 include a release coat thereon, then the extensions, (extensions 40, 41, 42 and 43, FIG. 1, and their analogues) will also be peelable.

In preferred embodiments, means are provided to facilitate stripping or peeling of at least one of the side gussets 6 and 7 from between the panels 4 and 5. Referring to FIG. 3, for preferred embodiments, this is accomplished by providing a substantial distance between an end seal and an associated bag end. Referring to FIG. 3, this is indicated by d_1 between end edge 31 and seal 35. In FIG. 1, it is also represented by d_2, between end

edge 30 and seal 34. Referring to FIG. 3, as a result of this substantial distance d_1, each strip, for example strip 6, is provided with a tab section 48 that can be easily gripped and manipulated. In general, a distance d_1 and-/or d_2 (FIG. 1) of about 0.5 to 1.5 inches, and preferably about 0.75 to 1.0 inches, is preferred for ease of gripping. A substantially smaller, i.e., less than about 0.5 inch, tab, or extension 48 would be difficult to easily grasp. A substantially larger (i.e., greater than about 1.5 inch) tab would be operable, but for many applications it would arguably involve a waste of material, i.e., a cutting down of the interior volume 23 of the bag 1, without provision of substantial advantage. In one alternate embodiment however, a relatively long tab is shown, providing for advantage, FIG. 6.

It is noted that advantages may be obtained by providing a pull tab such as tab 48 only at one end, either end 30 or end 31, of the bag 1. That is, a gusset 6 or 7 could easily be peeled if a pull tab is located at only one end thereof. Such an arrangement would allow for greater internal volume 23 with the same amount of outside material. In typical embodiments, however, pull tabs will be provided at opposite ends, i.e., ends 30 and 31, so that a user need not search for the pull tab 48.

It is also noted that bag 1 can be readily opened even if only one of gussets 6 and 7 is made peelable, i.e., if only one side gusset is provided with a release coat and at least one pull tab. However, in general, applications in which both of opposite gussets 6 and 7 are readily peelable are preferred, since bag 1 according to this arrangement is easily constructed and handled, and is more easily opened without searching.

The step of peeling a gusset, for example gusset 6, from between panels 4 and 5, will be best understood by comparison of FIGS. 1 and 4. In FIG. 4, gusset 6 is shown partly peeled or stripped from between panels 4 and 5. It will be readily understood that via this process, quick and easy access to article 24 within bag 1 can be readily obtained. From FIG. 4 it will be understood that advantages may be obtained even if the side gusset member is not stripped completely from association with the front and back panels. Therefore, when it is said herein that the side gusset is stripped "from between the panels" (or when similar statements are made) it is meant that the gusset is stripped sufficiently to open the bag for access to a stored item.

It is foreseen that in typical constructions, bag 1 will be prepared with seals 27 and 28 in place, and with one of seals 34 or 35 in place, prior to positioning an article 24 therein. After positioning of article 24 by passage through the open end (either 30 or 31,) the associated open end is then sealed closed.

It will be apparent that due to the non-integral (i.e. non-unitary) relationship between the gussets 6 and 7 and the panels 4 and 5, numerous advantages are obtained. The first of these, previously discussed, is that the gussets 6 and 7 can be constructed to be readily peelable or strippable from bag 1 for opening thereof. Another advantage is that unsightly seams in panels 4 and 5 are avoided. Yet another advantage is obtained from the fact that gussets 6 and 7 can be constructed from a material different than that used for panels 4 and 5. For example:

1. Strips 10 could be formed from a material having information indicia, advertising indicia or decorative indicia thereon. Production runs of bags 1 according to the present invention could be modified, for different indicia, by simply providing for different strips or gussets 6 and 7, without a change in the material used for panels 4 and 5.
2. The material utilized for gussets 6 and 7 could be made from a relatively strong, less flexible, material such as a metal foil or the like. Thus, in use gussets 6 and 7 could be folded open, to retain an open configuration, facilitating filling of an interior of bag 1 with material, especially relatively high profile material.
3. The material utilized for gussets 6 and 7, for certain preferred embodiments, can be a gas-permeable material, utilized to provide a bacteria filter for articles 24 stored within bag interior 23. Typically, conventional such gas-permeable materials comprising a high density spun bond polymeric material such as polypropylene or polyethylene would be utilized. One such material is available under the name TYVEK from DuPont. When the side gussets 6 and 7 are formed from such a material, bag 1 may be a readily sterilizable bag. That is, after an article 24 has been stored within interior 23, and the bag is sealed closed, the bag 1 and article 24 may be placed in a gaseous sterilizing environment such as an ethylene oxide environment. The ethylene oxide can readily permeate the gusset materials 6 and 7, to equilibrate within interior 23 and sterilize the environment thereof. The gas-permeable material, however, is generally sufficiently dense to prevent re-introduction of bacteria (contaminants) or the like, by acting as a filter therefor.

It will be generally understood that, especially for this last application of sterilization, bag constructions according to the present invention are particularly desirable. The expandable, accordion-like nature of the side gussets 6 and 7 facilitates wide open spreading and thus ease of gas introduction into bag interior 23. The easy opening, peelable, construction of the bag 1 facilitates operation in hospitals or the like, whereat access to contents such as surgical gowns, catheters, and other medical equipment stored within an interior of bag 1 may need to be accomplished within a brief period of time and completely by hand. The accordion-like nature of the side gussets 6 and 7 provides for a high profile on an interior of bag 1, and thus facilitates packaging therein of oddly configured or shaped articles. Positioning of gussets 6 and 7 on opposite sides 20 and 21 of bag 1 facilitates relatively rapid sterilizing gas introduction throughout all parts of interior 23 of bag 1.

It will be understood, however, that some advantages according to the present invention can be obtained from a construction 1 wherein gussets 6 and 7 are not formed from the same material. Also, a sterilizable bag can be made even with only one of gussets 6 or 7 comprising gas-permeable material. However, as indicated above, generally arrangements wherein both of side gussets 6 and 7 are gas-permeable, will be preferred.

In FIG. 5, an alternate bag construction 65 according to the present invention is illustrated. For the embodiment illustrated in FIG. 5, the bag 65 comprises a single panel member 67 having a single gusset 68 in association therewith. More specifically, panel member 67 comprises a unitary piece of material folded along edge line 69. Thus, there is no gusset member present along the side edge represented by edge line 69. A gusset member 68, analogous to gussets members 6 and 7, previously described, is fit in between edges 70 and 71 of panel 67. Seals analogous to those previously described for the preferred embodiment, are provided along opposite end

edges 72 and 73, as well as between the gusset member 68 and the panel edges 70 and 71. As with the preferred embodiment, a peelable arrangement between the gusset member 68 and the panel 67 can be provided, including a peelable arrangement having an easily gripped tab extension 75, in gusset member 68, to facilitate opening. The gusset member 68 may be constructed from a variety of materials, including those as previously described, and especially including a gas-permeable material such as TYVEK or the like. In some applications, it may be desirable to form the arrangement of FIG. 5 with peelable end seams 80 and 81. Such an arrangement could be easily opened like a book, for removal of stored articles without risk of contact between the stored article and residue adhesive at the opened seams. It is noted that such a variation is possible for the arrangement of FIGS. 1-3 as well.

In FIG. 6, yet another bag arrangement 100 according to the present invention is illustrated. Bag arrangement 100 includes end edges 101 and 102 and side edges 103 and 104. The side edges are sealed with gusset members 105 as previously described. Arrangement 100 is shown with only end 102 closed; however it will be understood that during use typically both ends 101 and 102 will be closed, at some point in the manufacturing process.

Still referring to FIG. 6, end 102 is closed by means of chevron seal 110. Thus, the embodiment of FIG. 6 demonstrates that an end seal need not be a strictly linear seal perpendicular to side edges 103 and 104. As a result of the chevron construction, relatively long tabs 111 are formed in areas 112 and 113, to facilitate opening through stripping of the gussets 105 from the bag 100.

In some circumstances, it may be desirable to form chevron seal 110 in a peelable manner. Thus, upper and lower panels 115 and 116 could be stripped apart from one another, along chevron seal 110. In this manner, articles held within the bag can be poured outwardly through end 102, when selected.

Spreading of panels 115 and 116 apart, along end seal 110, would be facilitated through use of side gussets according to the present invention. In particular, sections 111 and 112 of gussets 105 would be stripped back far enough to facilitate stripping of panels 115 and 116 from one another, along chevron seal 110.

It is to be understood that while certain embodiments of the present invention have been illustrated and described, it is not to be limited to the specific forms or arrangements herein described and shown.

What is claimed and desired to be secured by Letters Patent is as follows:

1. A bag arrangement comprising:

(a) a side panel arrangement including first and second, opposed, side panels defining first and second bag arrangement end edges and at least a first elongate side edge;

(b) an elongate gusset member positioned between said side panels and extending generally along said first elongate side edge;

(i) said gusset member having an elongate longitudinal hinge-fold therein; said hinge-fold defining: a central hinge-line oriented to project generally inwardly of said bag arrangement; and, first and second elongate gusset panels;

(ii) said gusset member being non-unitary with said panel arrangement and comprising a strip of gas-permeable material of sufficient density to function as a contaminant filter;

(c) first and second edge seam arrangements joining said gusset member to said first and second side panels; said first and second edge seam arrangements being peelable;

(d) a first end seam arrangement extending along a first one of said bag arrangement end edges; said first end seam arrangement including a central portion and first and second edge extensions;

(i) said first end seam arrangement central portion comprising a seam between said first and second side panels to substantially enclose a first of said bag arrangement end edges;

(ii) said first end seam arrangement first edge extension defining a peelable seam between said bag arrangement first side panel and said gusset member first gusset panel;

(iii) said first end seam arrangement second edge extension defining a peelable seam between said bag arrangement second side panel and said gusset member second gusset panel; and,

(e) said gusset member including an end tab extension projecting beyond said first end seam arrangement first and second edge extensions in a direction of a first one of said end edges; said end tab extension being of sufficient length to be readily grippable by a user of said bag arrangement to strip said gusset member from between said first and second side panels of said bag arrangement.

2. A bag arrangement according to claim 1 wherein said gusset member end tab extension is at least about 0.5 inches long.

3. A bag arrangement according to claim 1 wherein gusset member end tab extension is between about 0.5 and 1.5 inches long.

4. A bag arrangement according to claim 1 including a second end seam arrangement extending along a second one of said bag arrangement end edges; said second end seam arrangement including a central portion and first and second edge extensions;

(a) said second end seam arrangement central portion comprising a seam between said first and second panels to substantially enclose a second of said bag arrangement end edges;

(b) said second end seam arrangement first edge extension defining a peelable seam between said bag arrangement first side panel and said gusset member first gusset panel;

(c) said second end seam arrangement second edge extension defining a peelable seam between said bag arrangement second side panel and said gusset member second gusset panel.

5. A bag arrangement according to claim 4 wherein said gusset member includes a second end tab extension projecting beyond said second end seam arrangement first and second edge extensions in a direction of a second one of said end edges; said second end tab being of sufficient length to be readily grippable by a user of said bag arrangement, to strip said gusset member from said bag arrangement.

6. A bag arrangement according to claim 5 wherein said gusset member second end tab extension is at least about 0.5 inches long.

7. A bag arrangement according to claim 1 wherein said side panel arrangement first and second side panels comprise sections of a single folded sheet of material.

8. A bag arrangement according to claim 1 wherein said side panel arrangement first and second side panels comprise first and second independent sheets of material.

9. A bag arrangement comprising:

(a) a side panel arrangement including first and second, opposed, side panels defining first and second bag arrangement end edges and at least a first elongate side edge;

(i) said side panel arrangement first and second side panels comprising sections of a single folded sheet of material;

(b) an elongate gusset member positioned between said side panels and extending generally along said first elongate side edge;

(i) said gusset member having an elongate longitudinal hinge-fold herein; said hinge-fold defining: a central hinge-line oriented to project generally inwardly of said bag arrangement; and, first and second elongate gusset panels;

(ii) said gusset member being non-unitary with said panel arrangement;

(c) first and second edge seam arrangements joining said gusset member to said first and second side panels; said first and second edge seam arrangements being peelable;

(d) a first end seam arrangement extending along a first one of said bag arrangement end edges; said first end seam arrangement including a central portion and first and second edge extensions;

(i) said first end seam arrangement central portion comprising a seam between said first and second side panels to substantially enclose a first of said bag arrangement end edges;

(ii) said first end seam arrangement first edge extension defining a peelable seam between said bag arrangement first side panel and said gusset member first gusset panel;

(iii) said first end seam arrangement second edge extension defining a peelable seam between said bag arrangement second side panel and said gusset member second gusset panel; and,

(e) said gusset member including an end tab extension projecting beyond said first end seam arrangement first and second edge extensions in a direction of a first one of said end edges; said end tab extension being of sufficient length to be readily grippable by a user of said bag arrangement to strip said gusset member from between said first and second side panels of said bag arrangement.

10. A bag arrangement according to claim 9 wherein said gusset member end tab extension is at least about 0.5 inches long.

11. A bag arrangement according to claim 10 wherein gusset member end tab extension is between about 0.5 and 1.5 inches long.

12. A bag arrangement comprising:

(a) a side panel arrangement including first and second, independent, opposed, side panels defining first and second bag arrangement end edges, and first and second elongate side edges;

(b) a first elongate gusset member positioned between said side panels and extending generally along said first elongate side edge;

(i) said first gusset member having an elongate longitudinal hinge-fold therein; said hinge-fold defining: a central hinge-line oriented to project generally inwardly of said bag arrangement; and, first and second elongate gusset panels;

(ii) said first gusset member being non-unitary with said panel arrangement and comprising a strip of gas-permeable material of sufficient density to function as a contaminant filter;

(c) first and second seam arrangements joining said first gusset member to said first and second side panels; said first and second seam arrangements being peelable;

(d) a second elongate gusset member positioned between said side panels and extending generally along said bag arrangement second side edge;

(i) said second gusset member having an elongate longitudinal hinge-fold therein; said hinge-fold defining: a central hinge-line oriented to project generally inwardly of said bag arrangement; and, first and second elongate gusset panels;

(ii) said second gusset member being non-unitary with said panel arrangement; and

(d) third and fourth seam arrangements joining said second gusset member to said first and second side panels;

(e) a first end seam arrangement extending along a first one of said bag arrangement end edges; said first end seam arrangement including a central portion and first, second, third and fourth edge extensions;

(i) said first end seam arrangement central portion comprising a seam between said first and second side panels to substantially close a first of said bag arrangement end edges between said first and second gusset members;

(ii) said first end seam arrangement first edge extension defining a peelable seam between said bag arrangement first side panel and said first gusset member first gusset panel; and, said first end seam arrangement second edge extension defining a peelable seam between said bag arrangement second side panel and said first gusset member second gusset panel;

(iii) said first end seam arrangement third edge extension defining a seam between said bag arrangement first side panel and said second gusset member first gusset panel; and, said first end seam arrangement fourth edge extension defining a seam between said bag arrangement second side panel and said second gusset member second gusset panel; and,

(f) said first gusset member including a first end tab extension projecting beyond said first end seam arrangement first and second edge extensions; said first gusset member first end tab extension being of sufficient length to be readily grippable by a user of said bag arrangement, to strip said first gusset member from between said first and second side panels of said bag arrangement.

13. A bag arrangement according to claim 12 wherein said second gusset member is a strip of gas permeable material of sufficient density to function as a contaminant filter.

14. A bag arrangement according to claim 12 wherein said first gusset member first end tab extension is at least about 0.5 inches long.

15. A bag arrangement according to claim 14 wherein said first gusset member first end tab extension is between about 0.5 and 1.5 inches long.

16. A bag arrangement according to claim 12 wherein:
(a) said first end seam arrangement third and fourth edge extensions are peelable with respect to separation of said second gusset member from said first and second side panels; and,
(b) said second gusset member includes a first end tab extension projecting beyond said first end seam arrangement third and fourth edge extensions; said second gusset member first end tab extension being of sufficient length to be readily grippable by a user of said bag arrangement, to strip said second gusset member from between said first and second side panels of said bag arrangement.

17. A bag arrangement according to claim 16 including a second end seam arrangement extending along a second one of said bag arrangement end edges; said second end seam arrangement including a central portion and first, second, third and fourth edge extensions;
(i) said first end seam arrangement central portion comprising a second end seam between said first and second side panels to substantially close said second one of said bag arrangement end edges between said first and second gusset members;
(ii) said second end seam arrangement first edge extension defining a peelable seam between said bag arrangement first side panel and said first gusset member first gusset panel; and, said second end seam arrangement second edge extension defining a peelable seam between said bag arrangement second side panel and said first gusset member second gusset panel; and,
(iii) said second end seam arrangement third edge extension defining a seam between said bag arrangement first side panel and said second gusset member first gusset panel; and, said second end seam arrangement fourth edge extension defining a seam between said bag arrangement second side panel and said second gusset member second gusset panel.

18. A bag arrangement according to claim 17 wherein said side panel arrangement first and second side panels comprise first and second independent sheets of material.

19. A bag arrangement according to claim 17 wherein said second end seam arrangement third and fourth edge extensions each define a peelable seam with respect to said second gusset member.

20. A bag arrangement comprising:
(a) a side panel arrangement including first and second, opposed, side panels defining first and second bag arrangement end edges and at least a first elongate side edge;
(b) an elongate gusset member positioned between said side panels and extending generally along said first elongate side edge;
(i) said gusset member being non-unitary with said panel arrangement;
(ii) said gusset member comprising a strip of gas permeable material of sufficient density to function as a contaminant filter; and
(iii) said gusset member having an elongate longitudinal hinge-fold therein;
(c) means joining said gusset member to said first and second side panels; and,
(d) at least one of said gusset member and said side panel arrangement including a release coat having at least a portion thereof oriented along said bag arrangement first elongate side edge and between said gusset member and said side panel arrangement; said release coat providing for a readily peelable seam between said gusset member and said side panel arrangement.

21. A bag arrangement according to claim 20 wherein said side panel arrangement first and second side panels comprise portions of a single folded sheet of material.

22. A bag arrangement according to claim 21 wherein said side panel arrangement first and second side panels comprise first and second independent sheets of material.

23. A bag arrangement comprising:
(a) a side panel arrangement including first and second, opposed, side panels defining first and second bag arrangement end edges and at least a first elongate side edge;
(b) an elongate gusset member positioned between said side panels and extending generally along said first elongate side edge;
(i) said gusset member having an elongate longitudinal hinge-fold therein; said hinge-fold defining: a central hinge-line oriented to project generally inwardly of said bag arrangement; and, first and second elongate gusset panels;
(ii) said gusset member being non-unitary with said panel arrangement;
(iii) at least one of said gusset member and said side panel arrangement being provided with a release coat having at least a portion thereof oriented between said side panel arrangement first elongate side edge and said gusset member;
(c) first and second edge seam arrangements joining said gusset member to said first and second side panels; said first and second edge seam arrangements being readily peelable as a result of said release coat oriented between said side panel arrangement first elongate side edge and said gusset member;
(d) a first end seam arrangement extending along a first one of said bag arrangement end edges; said first end seam arrangement including a central portion and first and second edge extensions;
(i) said first end seam arrangement central portion comprising a seam between said first and second side panels to substantially enclose a first of said bag arrangement end edges;
(ii) at least one of said gusset member and said side panel arrangement including a release coat having at least a portion thereof oriented along said first end seam arrangement first edge extension and between said gusset member and said side panel arrangement; said first end seam arrangement first edge extension defining a readily peelable seam between said bag arrangement first side panel and said gusset member first gusset panel, as a result of said release coat along said first end seam arrangement first edge extension;
(iii) at least one of said gusset member and said side panel arrangement including a release coat with at least a portion thereof oriented along said first end seam arrangement second edge extension and between said gusset member and said side panel arrangement; said first end seam arrangement second edge extension defining a readily peelable seam between said bag arrangement second side panel and said gusset member second gusset panel, as a result of said release coat along

said first end seam arrangement second edge extension; and,

(e) said gusset member including an end tab extension projecting beyond said first end seam arrangement first and second edge extensions in a direction of a first one of said end edges; said end tab extension being at least about 0.5 inches long, so as to be readily grippable by a user of said bag arrangement to strip said gusset member from between said first and second side panels of said bag arrangement.

24. A bag arrangement according to claim **23** wherein said gusset member is a strip of gas-permeable material of sufficient density to function as a contaminant filter.

25. A bag arrangement according to claim **23** wherein gusset member end tab extension is between about 0.5 and 1.5 inches long.

26. A bag arrangement according to claim **23** wherein said side panel arrangement first and second side panels comprise sections of a single folded sheet of material.

27. A bag arrangement according to claim **23** wherein said side panel arrangement first and second side panels comprise first and second independent sheets of material.

28. A bag arrangement according to claim **23** wherein said gusset member is completely covered with said release coat.

29. A bag arrangement comprising:

(a) a side panel arrangement comprising a single folded sheet of material defining: first and second, opposed, side panels, first and second bag arrangement end edges; and, at least a first elongate side edge;

(b) an elongate gusset member positioned between said side panels and extending generally along said first elongate side edge;

(i) said gusset member being non-unitary with said panel arrangement; and,

(ii) said gusset member having an elongate longitudinal hinge-fold therein;

(c) means joining said gusset member to said first and second side panels; and,

(d) at least one of said gusset member and said side panel arrangement including a release coat having at least a portion thereof oriented along said bag arrangement first elongate side edge and between said gusset member and said side panel arrangement; said release coat providing for a readily peelable seam between said gusset member and said side panel arrangement.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,936,456

DATED : June 26, 1990

INVENTOR(S) : Gary M. Bell et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 2, line 6 "recontaminating" should read --re-contaminating--.

Column 3, line 21 "highprofile" should read --high-profile--.

Column 5, line 35 "is" should read --and--.

Column 13, line 20 "first" should read --second--.

Signed and Sealed this

Fifth Day of October, 1993

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks